NTP Historical Controls Report

By Route And Vehicle

RATS

May 2009

REPORT DESCRIPTION

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

This report is broken up into sections based on the route and vehicle used to deliver the chemical. The Table of Contents on Page 3 shows the different Route/Vehicle combinations. To see the data from all routes and vehicles combined into one set, you must run the "All Routes" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

Male	
	M1
	М2
	М3
	Μ4
	М5
Fema	ale
	F1
	F2
	F3
	F4
	г4 F5

the data would be shown as:

	Male			Female)
M1	M2	МЗ	F1	F2	F3
M4	M5		F4	F5	

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Page: 4

Report Date:04/29/2009

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical	
				Ma	ale			
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058810503 052000705 059902303 059902005	04/22/02 08/18/04 03/25/02 04/09/03	729 727 729 727	50 (3) 49 (3) 50 (3) 50 (3)	35(702) 34(692) 29(683) 39(685)	521.9 515.2 501.9 514.9	Isoeugenol Kava kava extract beta-Myrcene Pulegone	
				Fen	nale			
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058810503 052000705 059902303 059902005	04/23/02 08/19/04 03/26/02 04/10/03	730 728 730 728	50 (5) 50 (5) 50 (5) 50 (5)	33(699) 34(683) 31(668) 31(682)	339.3 354.3 323.8 341.2	Isoeugenol Kava kava extract beta-Myrcene Pulegone	

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

l Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Benign Tumors								
3		49/50 (98%) 47/50 (94%)	49/49 (100%)	49/50 (98%)		41/50 (82%) 42/50 (84%)	43/50 (86%)	40/50 (80%)
Overall Incidence	Total	194/199 (97.49%)	Mean 97.5%	SD 2.52%	Total	166/200 (83%)	Mean 83%	SD 2.58%
#All Organs: Malignant Tumors			•••••				•••••	
-		29/50 (58%) 10/50 (20%)	17/49 (35%)	23/50 (46%)		18/50 (36%) 8/50 (16%)	11/50 (22%)	11/50 (22%)
Overall Incidence	Total	79/199 (39.7%)	Mean 39.67%	SD 16.2%	Total	48/200 (24%)	Mean 24%	SD 8.49%
#All Organs: Malignant and Benign Tu	ımors							
		50/50 (100%) 47/50 (94%)	49/49 (100%)	50/50 (100%)		46/50 (92%) 44/50 (88%)	46/50 (92%)	45/50 (90%)
Overall Incidence	Total	196/199 (98.49%)	Mean 98.5%	SD 3%	Total	181/200 (90.5%)	Mean 90.5%	SD 1.91%
#All Organs: Hemangioma			•••••				•••••	
-		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#All Organs: Hemangiosarcoma								
		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 2%

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 5

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 6 Report Date:04/29/2009

Species: RATS Strain: F344

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE Vehicle: CORN OIL

				Ma	ale						Fem	ale		
All Organs:	manaiama													
Hemangiosarcoma or He	mangioma	1/50	(2%)	0/49	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	1/50	(2%)
		0/50	(0%)	0/10	(070)	0/00	(070)		2/50	(4%)	0,00	(070)	1,00	(270)
Overall Incidence	Total	1/199	,		0.5%	SD		Total		(1.5%)		n 1.5%		1.91%
All Organs: Histiocytic Sarcoma														
		0/50 0/50	(0%) (0%)	0/49	(0%)	1/50	(2%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/199	(0.5%)	Mean	0.5%	SD	1%	Total	0/200	(0%)	Mea	n 0%	SD	0%
All Organs: Leukemia: Erythrocytic					• • • • • • • • • • • • • • • • • • • •	•••••			•••••	•••••	• • • • • • • • • • • • • • • • • • • •		• • • • • • • • • • • • • • • • • • • •	
		0/50 0/50	(0%) (0%)	0/49	(0%)	0/50	(0%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/199	(0%)	Mean	0%	SD () %	Total	0/200	` '	Mea	n 0%	SD	0%
#All Organs: Leukemia: Lymphocytic, Undifferentiated	Monocytic, N	lononuclea	ar, or						••••••					
		10/50 4/50	(20%) (8%)	7/49	(14%)	9/50	(18%)		8/50 4/50	(16%) (8%)	5/50	(10%)	5/50	(10%)
Overall Incidence	Total		(15.08%)	Mean	15.07%	SD :	5.28%	Total	22/200	` '	Mea	n 11%	SD	3.46%
#All Organs: Malignant Lymphoma: Hi or Undifferentiated Cell T		nphocytic, 0/50 0/50	Mixed, NOS, (0%) (0%)	1/49	(2%)	1/50	(2%)		0/50 0/50	(0%) (0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total		(0%)		1.01%	0.0	1.17%	Total		(0.5%)		n 0.5%	SD	40/

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
All Organs: Mesothelioma: Benign								
-		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Benign, Mali						•••••	•••••	
-		3/50 (6%) 2/50 (4%)	3/49 (6%)	2/50 (4%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	10/199 (5.03%)	Mean 5.03%	SD 1.19%	Total	2/200 (1%)	Mean 1%	SD 1.15%
All Organs: Mesothelioma: Malignant								
Ū		3/50 (6%) 2/50 (4%)	3/49 (6%)	2/50 (4%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	10/199 (5.03%)	Mean 5.03%	SD 1.19%	Total	2/200 (1%)	Mean 1%	SD 1.15%
All Organs: Osteoma						•••••		
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma	•••••							
		2/50 (4%) 0/50 (0%)	1/49 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 1.63%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:04/29/2009

Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
All Organs: Osteosarcoma or Osteoma	<u> </u>							
		2/50 (4%) 0/50 (0%)	1/49 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 1.63%	Total	0/200 (0%)	Mean 0%	SD 0%
Adrenal Cortex: Adenoma				•••••				•••••
		0/50 (0%) 2/50 (4%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%
Adrenal Cortex: Carcinoma					•••••			
		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Ganglioneuroma				•••••				•••••
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Hemangioma				•••••				
3		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Adrenal Medulla: Pheochromocytoma Benign 5/50 (10%)(10%)(22%)2/50 (4%)(6%)(2%)8/50 (16%)3/50 (6%)29/199 (14.57%) 9/200 (4.5%) **Overall Incidence** Total Mean 14.55% SD 5.69% Total Mean 4.5% SD 1.91% *Adrenal Medulla: **Pheochromocytoma Complex** 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% 0/199 (0%) *Adrenal Medulla: Pheochromocytoma Malignant 3/50 (6%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 3% SD 0% Total 5/199 (2.51%) Mean 2.5% Total 0/200 (0%) Mean 0% *Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS 7/50 (14%)(10%)(26%)(6%)1/50 (2%)8/50 (16%)3/50 (6%)**Overall Incidence** 33/199 (16.58%) SD 6.74% SD 1.91% Total Mean 16.55% Total 9/200 (4.5%) Mean 4.5% #Bone: Chondrosarcoma 0/50 (0%)0/49 0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%)Mean 0% SD 0% Total 0/200 (0%)Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 10

			Male				Female	
#Bone: Chondrosarcoma or Cl	hondroma	0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Chordoma				1/50 (2%)				
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/199 (0.5%)	0/49 (0%) Mean 0.5%	SD 1%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma								
		2/50 (4%) 0/50 (0%)	1/49 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 1.63%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma or Oste								
		2/50 (4%) 0/50 (0%)	1/49 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 1.63%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 11

			Male				Female	
*Brain: Astrocytoma Malignant		0/50 (00/)	0/40 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Ependymoma Benign								•••••
		0/50 (0%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Ependymoma Malignant	•••••							
. ,		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Glioma Malignant					•••••			
3		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Granular Cell Tumor Benig								
2.2	y	0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 12

			Male				Female	
Brain: Medulloblastoma Mal								
Meduliobiastonia Mai		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant								•••••
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, Ma	lignant, NOS		(00)	(004)		0.50		(201)
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Beniq								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Malig								
		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 13

			Male				Female	
Brain:								
Oligodendroglioma, Gli	oma, or Astroc		0/40 (00/)	1/50 (20/)		1/50 (20/)	0/50 (00/)	0/50 (00/)
		1/50 (2%) 1/50 (2%)	0/49 (0%)	1/50 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Brain:		•••••				• • • • • • • • • • • • • • • • • • • •		
Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Schwannoma Malignant								
ochwannoma mangham	•	0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	, ,	, ,		0/50 (0%)	, ,	, ,
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland:								
Adenoma		0/50 /40/)	0/40 (00/)	E/E0 /400/)		0/40 (00/)	0/50 (40/)	7/50 (4.40/)
		2/50 (4%) 3/50 (6%)	0/49 (0%)	5/50 (10%)		3/48 (6%) 3/50 (6%)	2/50 (4%)	7/50 (14%)
Overall Incidence	Total	10/199 (5.03%)	Mean 5%	SD 4.16%	Total	15/198 (7.58%)	Mean 7.56%	SD 4.41%
Clitoral/Preputial Gland: Carcinoma								
		2/50 (4%) 1/50 (2%)	1/49 (2%)	0/50 (0%)		2/48 (4%) 0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 1.63%	Total	4/198 (2.02%)	Mean 2.04%	SD 2.36%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
*Clitoral/Preputial Gland: Carcinoma or Adenoma								
		4/50 (8%) 4/50 (8%)	1/49 (2%)	5/50 (10%)		5/48 (10%) 3/50 (6%)	4/50 (8%)	7/50 (14%)
Overall Incidence	Total	14/199 (7.04%)	Mean 7.01%	SD 3.44%	Total	19/198 (9.6%)	Mean 9.6%	SD 3.44%
Clitoral/Preputial Gland: Fibrosarcoma			•••••				•••••	
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/48 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/48 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/48 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Ear: Neural Crest Tumor					•••••			
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 15

			Male				Female	
#Esophagus: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Esophagus: Lipoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Eye:								•••••
Amelanotic Melanoma, B	enign	0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/30 (0%)		0/50 (0%)	0/30 (0%)	0/30 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Eye:								
Melanoma Malignant		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Eye:								
Schwannoma Malignant		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/199 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

ni. May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 16

			Male				Female	
Harderian Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Harderian Gland: Carcinoma or Adenoma								•••••
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Benign	•••••							
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Heart: Schwannoma Malignant								
-		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Large: Colon/Rectun Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Large: Colon/Rectur	m:							
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectur Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectur								
-		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyoma								
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Jejunum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Granular Cell Tumor M								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Leiomyoma					•••••			
·		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
ntestine Small: Jejunum: Leiomyosarcoma								
·		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ntestine Small: Site Unsp								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 18

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Small: Site Unsp								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp						•••••	•••••	•••••
	_	0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Leiomyoma	pecified:							
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Leiomyosarcoma	pecified:							
·		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma						•••••	•••••	
		4/50 (8%) 2/50 (4%)	4/49 (8%)	2/50 (4%)		0/50 (0%) 1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	12/199 (6.03%)	Mean 6.04%	SD 2.36%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 20

Report Date: 04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Islets, Pancreatic: Carcinoma 0/50 (0%)0/49 (0%)(2%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 **Overall Incidence** Total 1/199 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% *Islets. Pancreatic: Carcinoma or Adenoma 4/50 (8%)(6%)0/50 (0%)(2%)(2%)2/50 (4%)1/50 (2%)**Overall Incidence** Total 13/199 (6.53%)Mean 6.54% SD 1.96% Total 3/200 (1.5%) Mean 1.5% SD 1% *Kidney: Pelvis and Transitional Epithelium: Carcinoma 0/50 (0%)(0%)(2%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 1% SD 0% Total 1/199 (0.5%) Mean 0.5% Total 0/200 (0%) Mean 0% *Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/199 (0.5%) Mean 0.5% SD 1% SD 0% Total Total 0/200 (0%) Mean 0% *Kidney: Pelvis and Transitional Epithelium: **Papilloma** 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%)Mean 0% SD 0% Total 0/200 (0%)Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

11. May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 21

			Male				Female	
Kidney: Renal Tubule: Adenoma								
		0/50 (0%) 1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma				•••••				
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%) 1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
•		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Lipoma	•••••							
F		0/50 (0%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:04/29/2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344 Vehicle: CORN OIL Length of Study: CHRONIC

			Male				Female	
Kidney: Renal Tubule: Mesenchymal Tumor Be	nign							
·		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Nephroblastoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Kidney: Renal Tubule: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
_iver: Cholangioma							•••••	•••••
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Hemangiosarcoma								
•		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

1. Way 2000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 23

			Male				Female	
Liver: Hepatocellular Adenoma								
·		1/50 (2%) 1/50 (2%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Liver: Hepatocellular Carcinom	a	•••••		•••••				
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcinom	a or Hepatob	0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/199 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcinom	a or Hepatoc	ellular Adenoma 1/50 (2%) 1/50 (2%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Liver: Hepatocellular Carcinom Hepatoblastoma	a, Hepatocell	lular Adenoma, or						
		1/50 (2%) 1/50 (2%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male						Female	
*Lung: Alveolar/Bronchiolar Ade	noma							4550		
		3/50 (6% 0/50 (0%		3/50	(6%)		1/50 2/50	(2%) (4%)	0/50 (0%)	4/50 (8%)
Overall Incidence	Total	8/199 (4.02%	,	% SD	2.83%	Total	7/200	` ,	Mean 3.5%	SD 3.42%
*Lung: Alveolar/Bronchiolar Care	cinoma									
		1/50 (2% 1/50 (2%		0/50	(0%)		0/50 0/50	(0%) (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%) Mean 1.51	% SD	1.01%	Total	0/200	(0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Card Adenoma Overall Incidence	cinoma or Alv	4/50 (8% 1/50 (2% 10/199 (5.03)) 2/49 (4%)	3/50 % SD	(6%) 2.57%	Total	1/50 2/50 7/200	(2%) (4%) (3.5%)	0/50 (0%) Mean 3.5%	4/50 (8%) SD 3.42%
		10/100 (0.00								05 0.4270
*Lung: Fibrosarcoma										
		0/50 (0% 0/50 (0%		0/50	(0%)		0/50 0/50	(0%) (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD	0%	Total	1/200	(0.5%)	Mean 0.5%	SD 1%
*Lung: Hemangiosarcoma			•••••							
		1/50 (2% 0/50 (0%		0/50	(0%)		0/50 0/50	(0%) (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	6 SD	1%	Total		(0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 25

			Male				Female	
Lung: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lung: Squamous Cell Carcinoma	•••••							
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Lymph Node: Hemangiosarcoma								
·		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenolipoma	•••••			•••••				
·		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Mammary Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	4/200 (2%)	Mean 2%	SD 2.31%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 26

			Male				Female	
Mammary Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		4/50 (8%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	5/200 (2.5%)	Mean 2.5%	SD 3.79%
Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		4/50 (8%) 2/50 (4%)	3/50 (6%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	9/200 (4.5%)	Mean 4.5%	SD 3.42%
Mammary Gland: Fibroadenoma								
		4/50 (8%) 1/50 (2%)	0/49 (0%)	0/50 (0%)		26/50 (52%) 21/50 (42%)	24/50 (48%)	17/50 (34%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.5%	SD 3.79%	Total	88/200 (44%)	Mean 44%	SD 7.83%
Mammary Gland: Fibroma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenoma or								
		4/50 (8%) 1/50 (2%)	0/49 (0%)	0/50 (0%)		26/50 (52%) 22/50 (44%)	25/50 (50%)	17/50 (34%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.5%	SD 3.79%	Total	90/200 (45%)	Mean 45%	SD 8.08%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 27 Report Date: 04/29/2009

Species: RATS Strain: F344 Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Mammary Gland: Fibroma, Fibroadenoma,	Carcinoma, o	or Adenoma						
.,,	,	4/50 (8%) 1/50 (2%)	0/49 (0%)	0/50 (0%)		28/50 (56%) 22/50 (44%)	26/50 (52%)	17/50 (34%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.5%	SD 3.79%	Total	93/200 (46.5%)	Mean 46.5%	SD 9.71%
#Mesentery: Fibrosarcoma					•••••			
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma								
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Lipoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mesentery: Rhabdomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 28

			Male				Female	
Nose: Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Nose: Chondroma					•••••	•••••		
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Nose: Squamous Cell Carcino								
		0/50 (0%) 1/50 (2%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, Papilloma Squamous o	Tongue, Phary	nx, Tooth, Gingiva):						
		0/50 (0%) 0/50 (0%)	1/49 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Oral Cavity (Oral Mucosa, Squamous Cell Carcino	Tongue, Phary							
- 		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or **Papilloma** (2%)1/49 1/50 (2%)0/50 0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 2% Total 3/199 (1.51%) Mean 1.51% SD 1.01% Total 2/200 (1%) Mean 1% **#Oral Mucosa:** Squamous Cell Carcinoma 1/50 (2%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)(0%)(0%) 0/50 0/50 SD 1% SD 1% Overall Incidence Total 1/199 (0.5%) Mean 0.5% Total 1/200 (0.5%) Mean 0.5% **#Oral Mucosa: Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%) 0/50 0/50 **Overall Incidence** Total 2/199 (1.01%) Mean 1.01% SD 1.17% Total 0/200 (0%) Mean 0% SD 0% *Ovary: Cystadenoma 0/50 1/50 (2%)0/50 (0%)0/50 (0%)1/200 (0.5%) SD 1% **Overall Incidence** Total Mean 0.5% *Ovary: **Granulosa Cell Tumor Benign** 0/50 0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Male			Female	
*Ovary: Granulosa Cell Tumor Malignant				
C. a. a. soa oo a aa		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary:				
Granulosa Cell Tumor: Benign, Malignant, NOS		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Ovary:	•••••			
Granulosa-Theca Tumor Benign		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary:				
Granulosa-Theca Tumor Malignant		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary:				
Tubulostromal Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 31

			Male				Female	
Pancreas: Adenoma								
		7/50 (14%) 2/50 (4%)	1/49 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	11/199 (5.53%)	Mean 5.51%	SD 5.74%	Total	0/200 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma				•••••				
		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma								
		8/50 (16%) 2/50 (4%)	1/49 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	12/199 (6.03%)	Mean 6.01%	SD 6.72%	Total	0/200 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Benign								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 32

			Male				Female	
Parathyroid Gland: Adenoma								
		0/47 (0%) 1/49 (2%)	1/49 (2%)	1/45 (2%)		0/47 (0%) 2/46 (4%)	0/44 (0%)	0/47 (0%)
overall Incidence	Total	3/190 (1.58%)	Mean 1.58%	SD 1.05%	Total	2/184 (1.09%)	Mean 1.09%	SD 2.17%
Peripheral Nerve: Schwannoma Malignant					•••••			
_		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Peripheral Nerve: Schwannoma: Benign, Mal								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distalis Adenoma								
		19/50 (38%) 11/50 (22%)	21/49 (43%)	6/50 (12%)		25/50 (50%) 27/50 (54%)	29/50 (58%)	25/50 (50%)
Overall Incidence	Total	57/199 (28.64%)	Mean 28.71%	SD 14.27%	Total	106/200 (53%)	Mean 53%	SD 3.83%
Pituitary Gland: Pars Distalis Carcinoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Pituitary Gland: Pars Dista Carcinoma or Adenoma		ied Site:						
		19/50 (38%) 11/50 (22%)	21/49 (43%)	6/50 (12%)		25/50 (50%) 27/50 (54%)	30/50 (60%)	25/50 (50%)
Overall Incidence	Total	57/199 (28.64%)	Mean 28.71%	SD 14.27%	Total	107/200 (53.5%)	Mean 53.5%	SD 4.73%
*Pituitary Gland: Pars Dista Ganglioneuroma								
_		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Interr Adenoma	media:							
		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Interr Carcinoma	media:				••••••			
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Interr Carcinoma or Adenoma	media:						•••••	
2	-	1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 34

			Male				Female	
*Prostate: Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%				
Prostate: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%				
Salivary Glands: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Seminal Vesicle: Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%				
Skeletal Muscle: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 35
Report Date:04/29/2009

			Male				Female	
Skeletal Muscle: Hemangioma								
_		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle:								
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma	•••••							
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma or l								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

AGE

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Skeletal Muscle: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Adenoma							•••••	
		0/50 (0%) 0/50 (0%)	2/49 (4%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.02%	SD 2.04%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Skin: Basal Cell Adenoma or Ba	asosquamou	0/50 (0%)	2/49 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/50 (0%) 2/199 (1.01%)	Mean 1.02%	SD 2.04%	Total	0/50 (0%) 1/200 (0.5%)	Mean 0.5%	SD 1%
Skin: Basal Cell Adenoma, Basa Trichoepithelioma	osquamous '	Tumor Benign, or 0/50 (0%)	2/49 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
overall Incidence	Total	0/50 (0%) 2/199 (1.01%)	Mean 1.02%	SD 2.04%	Total	0/50 (0%) 1/200 (0.5%)	Mean 0.5%	SD 1%
		2/133 (1.0170)	Wicaii 1.0270			17200 (0.070)		
Skin: Basal Cell Carcinoma		4/50 (00/)	0/40 (00/)	4/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (00/)
		1/50 (2%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 37

				Male				Female		
#Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS)										
1100)		1/50 0/50	(2%) (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/199	` ,	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%	
#Skin: Basal Cell Carcinoma, Tumor (benign, maligr	Basal Cell Ader	noma, Basc	squamous	2/49 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
		0/50	(0%)	` ,	, ,		0/50 (0%)	,	,	
Overall Incidence	Total	4/199	(2.01%)	Mean 2.029	6 SD 1.67%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
	inoma, Carcinon oma, Adenoma,	Papilloma, pithelioma	Sq				0/00 (00)	(00)	WE (00)	
#Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan	inoma, Carcinon oma, Adenoma, tthoma, Trichoe	Papilloma, pithelioma 8/50 3/50	(16%) (6%)	2/49 (4%)	3/50 (6%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)	
#Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence	inoma, Carcinon oma, Adenoma, ithoma, Trichoe Total	Papilloma, pithelioma 8/50 3/50 16/199	(16%) (6%) (8.04%)	Mean 8.029	6 SD 5.4%	Total	1/50 (2%) 2/200 (1%)	Mean 1%	SD 1.15%	
or B), Basal Cell Aden	inoma, Carcinon oma, Adenoma, ithoma, Trichoe Total	Papilloma, pithelioma 8/50 3/50 16/199	(16%) (6%) (8.04%)	Mean 8.029	6 SD 5.4%		1/50 (2%) 2/200 (1%)	Mean 1%	SD 1.15%	
#Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence #Skin:	inoma, Carcinon oma, Adenoma, ithoma, Trichoe Total	Papilloma, pithelioma 8/50 3/50 16/199	(16%) (6%) (8.04%)	Mean 8.029	6 SD 5.4%		1/50 (2%) 2/200 (1%)	Mean 1%	SD 1.15%	
#Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence #Skin: Fibroma Overall Incidence	inoma, Carcinon oma, Adenoma, ithoma, Trichoe Total	Papilloma, pithelioma 8/50 3/50 16/199 5/50 3/50 18/199	(16%) (6%) (8.04%) (10%) (6%) (9.05%)	Mean 8.029 7/49 (14%) Mean 9.079	3/50 (6%) SD 3.95%	Total	1/50 (2%) 2/200 (1%) 0/50 (0%) 3/50 (6%) 6/200 (3%)	Mean 1% 1/50 (2%) Mean 3%	SD 1.15% 2/50 (4%) SD 2.58%	
#Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence #Skin: Fibroma Overall Incidence	inoma, Carcinon oma, Adenoma, ithoma, Trichoe Total	Papilloma, pithelioma 8/50 3/50 16/199 5/50 3/50 18/199	(16%) (6%) (8.04%) (10%) (6%) (9.05%)	Mean 8.029 7/49 (14%) Mean 9.079	3/50 (6%)	Total	1/50 (2%) 2/200 (1%) 0/50 (0%) 3/50 (6%) 6/200 (3%)	Mean 1% 1/50 (2%) Mean 3%	SD 1.15% 2/50 (4%) SD 2.58%	
#Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence #Skin: Fibroma Overall Incidence #Skin: Fibroma	inoma, Carcinon oma, Adenoma, ithoma, Trichoe Total	Papilloma, pithelioma 8/50 3/50 16/199 5/50 3/50 18/199	(16%) (6%) (8.04%) (10%) (6%) (9.05%)	Mean 8.029 7/49 (14%) Mean 9.079	3/50 (6%) SD 3.95%	Total	1/50 (2%) 2/200 (1%) 0/50 (0%) 3/50 (6%) 6/200 (3%)	Mean 1% 1/50 (2%) Mean 3%	SD 1.15% 2/50 (4%) SD 2.58%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Page: 38
Report Date: 04/29/2009

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
#Skin: Fibrosarcoma								
		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Skin: Fibrosarcoma, Sarcoma,								
Histiocytoma		2/50 (4%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Skin: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 39 Report Date:04/29/2009

Contract/Lab: All Laboratories

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
Skin:								
Keratoacanthoma		7/50 (14%) 3/50 (6%)	0/49 (0%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	12/199 (6.03%)	Mean 6%	SD 5.89%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Lipoma								
·		2/50 (4%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.92%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Liposarcoma								
·		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Neural Crest Tumor								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Neural Crest Tumor, Ma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 40

			Male				Female	
Skin: Neurofibroma or Schwan	noma benign							
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin:								
Neurofibrosarcoma or So	chwannoma (r	,						
		0/50 (0%) 3/50 (6%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 3%	Total	0/200 (0%)	Mean 0%	SD 0%
Neurofibrosarcoma, Neu malignant or NOS)	rofibroma, or	, ,				4-1-1		- 4
malignant or NOS)	r ofibroma, or Total	0/50 (0%) 3/50 (6%) 3/199 (1.51%)	0/49 (0%) Mean 1.5%	0/50 (0%) SD 3%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
malignant or NOS)	ŕ	0/50 (0%) 3/50 (6%)	0/49 (0%)	,	Total	0/50 (0%)	(333)	(,
malignant or NOS) verall Incidence Skin:	ŕ	0/50 (0%) 3/50 (6%)	0/49 (0%)	,	Total	0/50 (0%)	(333)	(,
malignant or NOS)	ŕ	0/50 (0%) 3/50 (6%) 3/199 (1.51%) 1/50 (2%)	0/49 (0%)	,	Total	0/50 (0%) 0/200 (0%) 	(333)	(,
malignant or NOS) verall Incidence Skin: Sarcoma	ŕ	0/50 (0%) 3/50 (6%) 3/199 (1.51%)	0/49 (0%) Mean 1.5%	SD 3%	Total Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
malignant or NOS) Everall Incidence Skin: Sarcoma Everall Incidence	Total	0/50 (0%) 3/50 (6%) 3/199 (1.51%) 1/50 (2%) 0/50 (0%)	0/49 (0%) Mean 1.5% 0/49 (0%)	SD 3%		0/50 (0%) 0/200 (0%) 	Mean 0%	SD 0% 0/50 (0%)
malignant or NOS) Overall Incidence Skin: Sarcoma Overall Incidence	Total	0/50 (0%) 3/50 (6%) 3/199 (1.51%) 1/50 (2%) 0/50 (0%) 2/199 (1.01%)	0/49 (0%) Mean 1.5% 0/49 (0%) Mean 1%	SD 3% 1/50 (2%) SD 1.15%		0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%) 0/200 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% 0/50 (0%) SD 0%
malignant or NOS) Overall Incidence Skin: Sarcoma Overall Incidence	Total	0/50 (0%) 3/50 (6%) 3/199 (1.51%) 1/50 (2%) 0/50 (0%)	0/49 (0%) Mean 1.5% 0/49 (0%)	SD 3%		0/50 (0%) 0/200 (0%) 	Mean 0%	SD 0% 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 41

Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Skin: Schwannoma Malignant								
·		0/50 (0%) 3/50 (6%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 3%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinom	a			•••••		•••••		
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinom Basosquamous Tumor (m	nalignant or N	1/50 (2%) 0/50 (0%)	0/49 (0%)	1/50 (2%)	Total	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	l	0/50 (00/)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Squamous Cell Papilloma	or Papillom	a		•••••				
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 42

Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male			Female	
#Skin: Squamous Cell Papillo Carcinoma or Keratoad		Squamous Cell					
		7/50 (14%) 3/50 (6%)	0/49 (0%)	2/50 (4%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/5	50 (0%)
Overall Incidence	Total	12/199 (6.03%)	Mean 6%	SD 5.89%	Total 1/200 (0.5%)		SD 1%
#Skin:							
Squamous Cell Papillo	oma, Papilloma,	or Keratoacanthoma 7/50 (14%) 3/50 (6%)	0/49 (0%)	2/50 (4%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/9	50 (0%)
Overall Incidence	Total	12/199 (6.03%)	Mean 6%	SD 5.89%	Total 1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Trichoepithelioma							
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5	50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total 0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma							
		1/50 (2%) 0/50 (0%)	0/49 (0%)	1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5	50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total 0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma							
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5	50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total 0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

II. Way2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 43

			Male				Female	
Skin: Sebaceous Gland: Carcinoma or Adenoma								
		1/50 (2%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
Spinal Cord: Astrocytoma Benign								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Spinal Cord: Astrocytoma Malignant				•••••		•••••		•••••
, ,		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spinal Cord: Glioma Malignant				•••••		•••••		•••••
-		0/50 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
Spleen: Fibrosarcoma	•••••				•••••			
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 44

Report Date:04/29/2009

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Spleen: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
pleen: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma	•••••							
-		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	2/200 (1%)	Mean 1%	SD 2%
pleen: Leiomyosarcoma						•••••		
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spleen: Sarcoma					•••••			
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

II. Way2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 45

			Male				Female	
#Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma					•••••			
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma o Overall Incidence	or Papillon Total	na Squamous 0/50 (0%) 0/50 (0%) 0/199 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/50 (2%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	0/50 (0%) SD 1%
Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)	•••••	0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Stomach, Glandular: Lipoma					• • • • • • • • • • • • • • • • • • • •			
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

11. May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 46

			Male				Female	
#Stomach, Glandular: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Testes: Adenoma								
		46/50 (92%) 46/50 (92%)	37/49 (76%)	47/50 (94%)				
Overall Incidence	Total	176/199 (88.44%)	Mean 88.38%	SD 8.63%				
Thymus: Sarcoma								•••••
		0/47 (0%) 0/50 (0%)	0/48 (0%)	0/47 (0%)		0/47 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/192 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
Thymus: Thymoma Benign								
, , , , , ,		0/47 (0%) 0/50 (0%)	0/48 (0%)	0/47 (0%)		0/47 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
overall Incidence	Total	0/192 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
Thymus: Thymoma Malignant					•••••			
,		0/47 (0%) 0/50 (0%)	0/48 (0%)	0/47 (0%)		0/47 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/192 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Carcinoma

Overall Incidence

Overall Incidence

*Thyroid Gland: C-Cell: Carcinoma or Adenoma

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Female Male *Thymus: **Thymoma NOS** 0/47 (0%)0/48 (0%)(0%)0/47 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 **Overall Incidence** Total 0/192 (0%) Mean 0% SD 0% Total 0/196 (0%) Mean 0% SD 0% *Thymus: Thymoma: Benign, Malignant, NOS 0/47 (0%)0/47 (0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/192 (0%) Mean 0% SD 0% Total 0/196 (0%) Mean 0% SD 0% *Thyroid Gland: C-Cell: Adenoma 9/50 (18%)(16%)(24%)7/50 (14%)5/50 (10%)(10%)8/50 (16%)8/50 (16%) **Overall Incidence** (12.5%)SD 3% Total 37/199 (18.59%) Mean 18.58% SD 3.72% Total 25/200 Mean 12.5% *Thyroid Gland: C-Cell:

(0%)

(24%)

SD 6.72%

SD 6%

3/50

0/50

9/50

8/50

27/200

Total

Total

3/200 (1.5%)

(6%)

(0%)

(18%)

(16%)

(13.5%)

0/50

5/50

(0%)

(10%)

Mean 13.5%

Mean 1.5%

0/50

SD 3%

(0%)

(10%)

SD 4.12%

*: [Denominator	is number	of anim	als with	tissues	examined	l microscopio	ally
------	-------------	-----------	---------	----------	---------	----------	---------------	------

Total

Total

(12%)

(30%)

(16%)

(21.61%)

Mean 3%

(16%)

Mean 21.58%

(0%)

6/50

0/50

15/50

8/50

43/199

6/199 (3.02%)

Page: 47

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Thyroid Gland: Follicular Cell: Adenoma								
		1/50 (2%) 0/50 (0%)	1/49 (2%)	1/50 (2%)		/50 (0%) /50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.51%	SD 1.01%		00 (0.5%)	Mean 0.5%	SD 1%
*Thyroid Gland: Follicular Cell: Carcinoma								
		1/50 (2%) 0/50 (0%)	0/49 (0%)	2/50 (4%)		/50 (2%) /50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total 1/20	00 (0.5%)	Mean 0.5%	SD 1%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		2/50 (4%) 0/50 (0%)	1/49 (2%)	3/50 (6%)		/50 (2%) /50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	6/199 (3.02%)	Mean 3.01%	SD 2.58%		00 (1%)	Mean 1%	SD 1.15%
#Tissue NOS: Lipoma								
·		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		/50 (0%) /50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%		00 (0%)	Mean 0%	SD 0%
#Tissue NOS: Paraganglioma	•••••							
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		/50 (0%) /50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%		00 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

May2009 Toxicol

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 49

			Male				Female	
#Tissue NOS: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinom					•••••			
•		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinom		na Squamous						
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Tongue: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Tooth: Adamantinoma Malignan	t							
g		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/30 (0%)				0/30 (0/8)		SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 50

			Male				Female	
#Tooth: Odontoma		0/50 (00/)	0/40 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Urinary Bladder: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma					•••••			
		0/50 (0%) 0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Leiomyosarcoma								
,		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Urinary Bladder: Papilloma 0/50 0/49 (0%)(2%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 **Overall Incidence** Total 1/199 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% #Uterus: Adenoma 0/50 (0%)(0%)(0%)0/50 (0%) **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Uterus: Carcinoma 0/50 (0%)0/50 (0%)(2%)0/50 (0%)**Overall Incidence** SD 1% Total 1/200 (0.5%)Mean 0.5% **#Uterus:** Deciduoma Benign (0%) 1/50 0/50 (0%)0/50 0/50 (0%)**Overall Incidence** (0.5%)Mean 0.5% SD 1% Total 1/200 #Uterus: Hemangioma (0%) 0/50 (0%)0/50 0/50 (0%)**Overall Incidence** Total 0/200 (0%)Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Tumor Incidence for Selected Control Animal Groups

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Route: GAVAGE Vehicle: CORN OIL Page: 52

	Male				Female	
Uterus:						
Hemangiosarcoma			0/50	(0%)	0/50 (0%)	0/50 (0%)
			0/50	(0%)	0,00 (0,70)	0/00 (0/0)
verall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
			•••••	• • • • • • • • • • • • • • • • • • • •		
Uterus: Leiomyoma						
Loidinyonia			0/50	(0%)	0/50 (0%)	0/50 (0%)
			0/50	(0%)		
verall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
Uterus:			•••••	• • • • • • • • • • • • • • • • • • • •		
Leiomyosarcoma						
			0/50 0/50	(0%) (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (` '	Mean 0%	SD 0%
Uterus:						
Polyp Stromal			8/50	(16%)	7/50 (14%)	8/50 (16%)
			5/50	(10%)	(11,	(111,
Overall Incidence		Total		(14%)	Mean 14%	SD 2.83%
Uterus:						
Sarcoma Stromal						
			0/50 0/50	(0%) (0%)	1/50 (2%)	0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Uterus: Sarcoma Stromal or Po	lyp Stromal							
						8/50 (16%) 5/50 (10%)	7/50 (14%)	8/50 (16%)
verall Incidence					Total	28/200 (14%)	Mean 14%	SD 2.83%
Jterus:								
Schwannoma Malignan	t					0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence					Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
······································								
Vagina:								
Polyp						1/50 (2%)	0/50 (0%)	0/50 (0%)
overall Incidence					Total	0/50 (0%) 1/200 (0.5%)	Mean 0.5%	SD 1%
Vagina:								
Sarcoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
					-	0/50 (0%)	NA 00/	OD 00/
verall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%
Zymbal's Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 54

			Male			Female			
#Zymbal's Gland: Carcinoma									
		2/50 (4%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	
#Zymbal's Gland: Carcinoma or Adenoma			•••••						
		2/50 (4%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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Report Date:04/29/2009

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Southern Research Institute Southern Research Institute	059902407 059100507	02/03/03 06/26/00	729 730	50 (3) 50 (3)	21(661) 30(693)	518.7 520.6	Androstenedione Methylene blue trihydrate
				Fen	nale		
Southern Research Institute Southern Research Institute	059902407 059100507	02/03/03 06/26/00	729 733	50 (5) 50 (5)	38(710) 35(699)	356.5 335.9	Androstenedione Methylene blue trihydrate

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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			Male				Female	
All Organs: Benign Tumors								
Overall Incidence	Total	47/50 (94%) 94/100 (94%)	47/50 (94%) Mean 94%	SD 0%	Total	44/50 (88%) 91/100 (91%)	47/50 (94%) Mean 91%	SD 4.24%
		` ,				` ,		
All Organs: Malignant Tumors			20/20 (2001)			(000)	10(70 (000))	
Overall Incidence	Total	34/50 (68%) 64/100 (64%)	30/50 (60%) Mean 64%	SD 5.66%	Total	10/50 (20%) 29/100 (29%)	19/50 (38%) Mean 29%	SD 12.73%
verali iliciuelice		,						
All Organs: Malignant and Benign Tumo								
verall Incidence	Total	49/50 (98%) 98/100 (98%)	49/50 (98%) Mean 98%	SD 0%	Total	46/50 (92%) 96/100 (96%)	50/50 (100%) Mean 96%	SD 5.66%
		,				` ,		
All Organs: Hemangioma		0/50 (0%)						
verall Incidence	Total	1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
All Organs: Hemangiosarcoma		4/50 (00/)	4/50 (00()			0/50 (00)	4/50 (00()	
verall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
		2,100 (270)	WIOGII 270		10101	.,,,,,	Would 170	35 1.4170
All Organs: Hemangiosarcoma or Hema	ngioma	4/50 (00/)	0/50 (404)			0/50 (00)	4/50 (00()	
verall Incidence	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
veran incluence	Total	3/100 (370)	IVICALI 370	SD 1.4170	Total	1/100 (170)	IVICALI 170	SD 1.4170

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#All Organs: Histiocytic Sarcoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#All Organs: Leukemia: Erythrocytic	•••••	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic, N Undifferentiated	lonocytic, Mo	ononuclear, or						
Overall Incidence	Total	26/50 (52%) 49/100 (49%)	23/50 (46%) Mean 49%	SD 4.24%	Total	5/50 (10%) 17/100 (17%)	12/50 (24%) Mean 17%	SD 9.9%
#All Organs: Malignant Lymphoma: His or Undifferentiated Cell Ty	tiocytic, Lym							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign		0/50 (00/)	0/50 (0%)			0/50 (0%)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs: Mesothelioma: Benign, Ma	lignant, NOS		2/50 /69/)			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	1/50 (2%) 4/100 (4%)	3/50 (6%) Mean 4%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

Page: 58

			Male				Female	
#All Organs: Mesothelioma: Malignant Overall Incidence	nt 1/50 (2%) Total 4/100 (4%)		3/50 (6%) Mean 4%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#All Organs: Osteoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
Osteosarcoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#All Organs:								
Osteosarcoma or Osteoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Adrenal Cortex:						•••••		
Adenoma		3/50 (6%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Adrenal Cortex:								•••••
Carcinoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall illelidelide	i Ulai	0/100 (0/0)	IVICALI U/0			` ,	ivicaii 076	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Adrenal Medulla: Ganglioneuroma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benign		7/50 (14%)	9/50 (18%)			3/50 (6%)	2/50 (4%)	
Overall Incidence	Total	16/100 (16%)	Mean 16%	SD 2.83%	Total	5/100 (5%)	Mean 5%	SD 1.41%
*Adrenal Medulla: Pheochromocytoma Comple	x	1/50 (2%)	1/50 (2%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Adrenal Medulla: Pheochromocytoma Maligna	nt	0/50 (00/)	4/50 (00)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma: Benign			11/50 (22%)			4/50 (8%)	2/50 (4%)	
Overall Incidence	Total	19/100 (19%)	Mean 19%	SD 4.24%	Total	6/100 (6%)	Mean 6%	SD 2.83%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Strain: F344 Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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		Male				Female	
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
droma							
Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (/0//)	0/50 (0%)			0/50 (/0//)	0/50 (00/)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
	4/50 (00)	0/50 (00/)			0/50 (00/)	4/50 (00)	
Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
	Total Total Total	7 John March 1 John 1 J	O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% Aroma O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% 1/50 (2%) O/50 (0%) Total 1/100 (1%) Mean 1% O/50 (0%) Total O/100 (0%) Mean 0% 1/50 (2%) O/50 (0%) Mean 1% 1/50 (2%) O/50 (0%) Mean 1%	O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% SD 0% droma O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% SD 0% 1/50 (2%) O/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% SD 0% Total 1/50 (2%) O/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41%	Total 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total droma 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total 1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total	Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Afroma 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Total 1/50 (2%) 0/50 (0%) Total 0/100 (0%) Mean 1% SD 1.41% Total 0/100 (0%) Total 1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total 1/100 (1%) Total 1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total 1/100 (1%)	Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% Ifoma O/50 (0%) 0/50 (0%) Mean 0% Total 0/100 (0%) Mean 0% Total 0/100 (0%) 0/50 (0%) Mean 0% Total 0/100 (0%) Mean 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% Total 1/50 (2%) 0/50 (0%) Mean 1% SD 1.41% Total 0/100 (0%) Mean 0% Total 1/50 (2%) 0/50 (0%) Mean 0% Total 1/50 (2%) 0/50 (0%) Total 1/100 (1%) Mean 1% Total 1/50 (2%) 0/50 (0%) Mean 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: METHYLCELLULOSE

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Report Date:04/29/2009

			Male				Female	
*Brain: Astrocytoma Malignant		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Ependymoma Benign		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Ependymoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Glioma Malignant Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Granular Cell Tumor Benig Overall Incidence	n Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Medulloblastoma Mal		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Brain: Meningioma Malignant		0/50 (00/)	0/50 /00/			0/50 (00/)	0/50 (00()	_
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Meningioma: Benign, Maliç	gnant, NOS	0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Oligodendroglioma Benigr	n	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/30 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Oligodendroglioma Malign	ant	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Oligodendroglioma, Gliom	a, or Astroc		0/50 /00/			0/50 (00/)	0/50 (00()	
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Osteosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Brain: Schwannoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma		3/50 (6%)	1/50 (2%)			12/50 (24%)	7/50 (14%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	19/100 (19%)	Mean 19%	SD 7.07%
*Clitoral/Preputial Gland: Carcinoma		0/50 (0%)	0/50 (0%)			4/50 (00()	4/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma		3/50 (6%)	1/50 (2%)			13/50 (26%)	8/50 (16%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	21/100 (21%)	Mean 21%	SD 7.07%
*Clitoral/Preputial Gland: Fibrosarcoma		0/50 (00/)	0/50 (00/)			0/50 (00)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Sarcoma	•••••	0/50 (004)	0/50 (00/)			4/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

1. May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Papillom		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Ear: Neural Crest Tumor					•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Esophagus: Fibrosarcoma	•••••	0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Esophagus: Lipoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Eye: Amelanotic Melanoma, B	enign				•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Eye: Melanoma Malignant	•••••	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Eye: Schwannoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Benign		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Malignant		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Large: Colon/Rectur Adenoma			0/50 (0%)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Intestine Large: Colon/Rectur Carcinoma	n:	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectur Carcinoma or Adenoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Large: Colon/Rectur Hemangioma							0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyoma	•••••				••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma	•••••	(201)			•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

lay2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Intestine Small: Jejunum: Granular Cell Tumor Ma		0/50 /00/	0/50 /00/			0/50 (00/.)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma		0/50 (00)	0/50 /00/			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unsp Carcinoma	ecified:	(20)	(20)			(201)	(00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Unsp Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Unsp Granular Cell Tumor Ma		(00)	(20)				(00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		` '				` ,		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Site Unspeci Leiomyoma	fied:	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspeci Leiomyosarcoma			0/50 (0%)			0/50 (00/)	0/50 /00/	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma		4/50 (8%)	4/50 (8%)			1/50 (2%)	2/49 (4%)	
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 0%	Total	3/99 (3.03%)	Mean 3.04%	SD 1.47%
*Islets, Pancreatic: Carcinoma		0/50 (0%)	0/50 (0%)		•••••	1/50 (2%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
*Islets, Pancreatic: Carcinoma or Adenoma		4/50 (00()	4/50 (00/)			0/50 (40())	0/40 /40/	
Overall Incidence	Total	4/50 (8%) 8/100 (8%)	4/50 (8%) Mean 8%	SD 0%	Total	2/50 (4%) 4/99 (4.04%)	2/49 (4%) Mean 4.04%	SD 0.06%
*Kidney: Pelvis and Transition Carcinoma		n:						
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Kidney: Pelvis and Transition Carcinoma or Adenoma	nal Epitheliu	m:						
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Pelvis and Transitior Papilloma		m:			•••••			
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma				•••••				
		0/49 (0%)	0/50 (0%)	OD 00/		0/50 (0%)	0/50 (0%)	25. 22/
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma								
		0/49 (0%)	0/50 (0%)	OD 00/		0/50 (0%)	0/50 (0%)	25. 22/
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
	-	0/49 (0%)	0/50 (0%)	00.00/	-	0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Strain: F344 Vehicle: METHYLCELLULOSE Length of Study: CHRONIC

Report Date:04/29/2009

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			Male				Female	
*Kidney: Renal Tubule: Lipoma			2/22 (22()			2/22 (22)	0/50 (00/)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Benigr	n	0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Nephroblastoma		0/40 (00/)	0/50 (00/)			0/50 (0%)	0/50 (00/)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma		0/40 (00/)	0/50 (00/)			0/50 (00)	0/50 (00/)	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Cholangioma		0/50 (00/)	0/50 (00/)			0/50 (0%)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hemangiosarcoma		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
*Liver: Hepatocellular Adenoma	a	2/50 (4%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinon								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hepatocellular Carcinon	na or Hepatob		0/50 (09/)			0/50 (09/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Hepatocellular Carcinon	na or Hepatoco	ellular Adenoma 2/50 (4%)	1/50 (2%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinon Hepatoblastoma								
Overall Incidence	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Ad	enoma	0/50 (00()	4/50 (00()			0/50 (00/)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
Lung: Alveolar/Bronchiolar Carcin	oma	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Lung: Alveolar/Bronchiolar Carcin Adenoma	oma or Alv	veolar/Bronchiolar						
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Lung: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Lung: Hemangiosarcoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
Lung: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Lung: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

			Male			0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% 1/50 (2%) 1/50 (2%) Total 2/100 (2%) Mean 2% SD 0% 2/50 (4%) 1/50 (2%) Total 3/100 (3%) Mean 3% SD 1.4 3/50 (6%) 2/50 (4%) Total 5/100 (5%) Mean 5% SD 1.4		
#Lymph Node: Hemangiosarcoma		1/50 (2%)	0/50 (0%)			` ,	` ,	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenolipoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` ,	` '	SD 0%
#Mammary Gland: Adenoma	• • • • • • • • • • • • • • • • • • • •				•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total		` '	SD 0%
#Mammary Gland: Carcinoma		0/50 (0%)	0/50 (0%)			2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total		` ,	SD 1.41%
#Mammary Gland: Carcinoma or Adenoma		0.750 (001)					-/ (101)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` '	SD 1.41%
#Mammary Gland: Fibroadenoma		2/50 (4%)	2/50 (4%)			35/50 (70%)	28/50 (56%)	
Overall Incidence	Total	4/100 (4%)	Mean 4%	SD 0%	Total	63/100 (63%)	Mean 63%	SD 9.9%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:04/29/2009

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male			36/50 (72%) 29/50 (58%) I 65/100 (65%) Mean 65% SD 9.9% 37/50 (74%) 30/50 (60%)				
#Mammary Gland: Fibroma		1/50 (2%)	0/50 (0%)			0/50 (09/)	0/50 (0%)			
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	` ,	` ,	SD 0%		
#Mammary Gland: Fibroma, Fibroadenon	na or Adenoma	3/50 (6%)	2/50 (4%)			36/50 (72%)	20/50 /599/\			
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	, ,	, ,	SD 9.9%		
#Mammary Gland: Fibroma, Fibroadenon			2/50 (4%)							
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 1.41%	Total	67/100 (67%)	Mean 67%	SD 9.9%		
#Mesentery: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%		
#Mesentery: Hemangiosarcoma	•••••									
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
#Mesentery: Lipoma	•••••	0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

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			Male				Female	
#Mesentery: Rhabdomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Nose: Adenoma		(201)	2/22 (221)			(201)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Nose: Chondroma		0/50 (00/)	0/50 (00/)			0/50 /00/	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Nose: Squamous Cell Carcinor								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, 1 Papilloma Squamous or	Гongue, Phary							
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, 1 Squamous Cell Carcinor	Гongue, Phary	vnx, Tooth, Gingiva):						
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma	Tongue, Phary oma, Papilloma	nx, Tooth, Gingiva): Squamous, or						
		1/50 (2%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Oral Mucosa: Squamous Cell Carcino	oma							
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Oral Mucosa: Squamous Cell Papillo	ma	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Cystadenoma						0/50 (0%)	0/50 (00/)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor I	Benign							
Overall Incidence	-				Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor I	Malignant					(200)		
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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	Male					Female				
*Ovary: Granulosa Cell Tumor:	Benign, Malign	ant, NOS				0/50 (00/)	0/50 (00/)			
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Ovary:	- D!									
Granulosa-Theca Tumo Overall Incidence	_				Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Ovary: Granulosa-Theca Tumo						0/50 (0%)	0/50 (0%)			
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%		
*Ovary: Tubulostromal Adenom										
Overall Incidence					Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%		
*Pancreas: Adenoma		3/50 (6%)	0/50 (0%)			0/50 (0%)	1/49 (2%)			
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%		
*Pancreas: Carcinoma		(00)	(00)			2/22 (22)	(201)			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

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Report Date:04/29/2009

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Pancreas: Carcinoma or Adenoma		3/50 (6%)	0/50 (0%)			0/50 (0%)	1/49 (2%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%
*Pancreas: Mixed Tumor Benign		0/50 (0%)	1/50 (2%)		•••••	0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%
*Pancreas: Mixed Tumor Malignant		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Parathyroid Gland: Adenoma		0/48 (0%)	0/50 (0%)			0/49 (0%)	0/47 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma Malignant			4/EO (20/)			0/50 //00/	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign, Mal	ignant, NOS		4/50 (00()			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Pituitary Gland: Pars Distalis o	or Unspecif	ied Site:						
		19/50 (38%)	25/50 (50%)			19/50 (38%)	36/50 (72%)	
Overall Incidence	Total	44/100 (44%)	Mean 44%	SD 8.49%	Total	55/100 (55%)	Mean 55%	SD 24.04%
•••••	•••••							
*Pituitary Gland: Pars Distalis o Carcinoma	or Unspecif	ied Site:						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Distalis				•••••	••••••			
Carcinoma or Adenoma		10/50 (200/)	0E/E0 /E00/\			10/50 (200/)	26/50 (720/)	
Overell Insidence	Tatal	19/50 (38%)	25/50 (50%)	CD 0.400/	Tatal	19/50 (38%)	36/50 (72%)	CD 04 040/
Overall Incidence	Total	44/100 (44%)	Mean 44%	SD 8.49%	Total	55/100 (55%)	Mean 55%	SD 24.04%
• • • • • • • • • • • • • • • • • • • •	• • • • • • • • • • • • • • • • • • • •				• • • • • • • • • • • • • • • • • • • •			
*Pituitary Gland: Pars Distalis	or Unspecif	ied Site:						
Ganglioneuroma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Intermed	ia:							
Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Intermed	ia:				•••••			
Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Overan incluence	i Ulai	0/100 (0/0)	IVICALI U/0	3D 0/0	i Ulai	0/100 (0/0)	IVICALL U/0	3D 0/0

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Pituitary Gland: Pars Intermed Carcinoma or Adenoma	dia:	0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma		0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Prostate: Carcinoma or Adenoma		0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%				
*Salivary Glands: Sarcoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma		0/50 (00/)	0/50 (0%)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
#Skeletal Muscle: Fibrous Histiocytoma	•••••	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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		Male				Female	
	0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (09/)	0/50 (/0//)		•••••	0/50 (00/)	0/50 (00/)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	a						
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (00%)	0/50 (00()			0/50 (00/)	0/50 (00)	
Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	Total Total habdomyom	0/50 (0%) Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) 0/50 (0%) Total 0/100 (0%) habdomyoma 0/50 (0%) Total 0/100 (0%)	O/50 (0%) 1/50 (2%) Total 1/100 (1%) Mean 1% O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% Total O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0% habdomyoma O/50 (0%) O/50 (0%) Total O/100 (0%) Mean 0%	Total 1/100 (1%) 1/50 (2%) Total 1/100 (1%) Mean 1% SD 1.41% 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% habdomyoma 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0%	Total 1/100 (1%)	0/50 (0%) 1/50 (2%) SD 1.41% Total 0/50 (0%) Total 1/100 (1%) Mean 1% SD 1.41% Total 0/100 (0%) Total 0/50 (0%) 0/50 (0%) SD 0% Total 0/100 (0%) Total 0/50 (0%) 0/50 (0%) SD 0% Total 0/100 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) habdomyoma 0/50 (0%) 0/50 (0%) SD 0% Total 0/100 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) 0/50 (0%) 0/50 (0%) SD 0% Total 0/100 (0%)	Total 1/100 (1%) Mean 1% SD 1.41% Total 0/50 (0%) 0/50 (0%) Mean 0% Total 0/100 (0%) 0/50 (0%) Mean 0% Total 0/100 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/100 (0%) 0/50 (0%) Mean 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) 0/50 (0%) Mean 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male			0/50 (0%) 0/50 (0%) al 0/100 (0%) Mean 0% SD 0% 0/50 (0%) 1/50 (2%) al 1/100 (1%) Mean 1% SD 1.41% 0/50 (0%) 1/50 (2%)			
#Skin: Basal Cell Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` ,	` ,	SD 0%	
‡Skin: Basal Cell Adenoma or	Basosquamou								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` '	` '	SD 0%	
#Skin: Basal Cell Adenoma, Ba Trichoepithelioma			0/50 (0%)						
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%		
#Skin: Basal Cell Carcinoma									
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	` ,	` '	SD 1.41%	
#Skin: Basal Cell Carcinoma o NOS)									
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	
Skin: Basal Cell Carcinoma, I Tumor (benign, maligna	Basal Cell Ader	noma, Basosquamous	0/50 (0%)			0/50 (0%)	2/50 (4%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Species: RATS Strain: F344 Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female				
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 5/50 (10%) 7/50 (14%) 0/50 (0%) 3/50 (6%)											
Overall Incidence	Total	12/100 (12%)	Mean 12%	SD 2.83%	Total	3/100 (3%)	Mean 3%	SD 4.24%			
Skin: Fibroma	•••••										
Overall Incidence	Total	5/50 (10%) 11/100 (11%)	6/50 (12%) Mean 11%	SD 1.41%	Total	3/50 (6%) 4/100 (4%)	1/50 (2%) Mean 4%	SD 2.83%			
Skin: Fibroma, Fibrosarcoma, Fibrous Histiocytoma verall Incidence	Sarcoma, My	xoma, M yxosarcoma, o 6/50 (12%) 14/100 (14%)	r 8/50 (16%) Mean 14%	SD 2.83%	Total	3/50 (6%) 5/100 (5%)	2/50 (4%) Mean 5%	SD 1.41%			
Skin: Fibrosarcoma		1/50 (2%)	3/50 (6%)			0/50 (0%)	1/50 (2%)				
verall Incidence	Total	4/100 (4%)	Mean 4%	SD 2.83%	Total	1/100 (1%)	Mean 1%	SD 1.41%			
Skin: Fibrosarcoma, Sarcoma, Histiocytoma	Myxosarcom	,	0/50 (00/)			0/50 (00/)	4/50 (00)				
Overall Incidence	Total	1/50 (2%) 4/100 (4%)	3/50 (6%) Mean 4%	SD 2.83%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%			
Skin: Fibrous Histiocytoma		0/50 (00/)	0/50 (00)			0/50 (00)	0/50 (00/)				
		0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%		0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Strain: F344

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

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			Male			0/50 (0%) 1/50 (2%) I 1/100 (1%) Mean 1% SD 1.41% 0/50 (0%) 0/50 (0%)			
#Skin: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` '	` '	SD 0%	
#Skin: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (294)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` '	(,	SD 1.41%	
#Skin: Keratoacanthoma		3/50 (6%)	3/50 (6%)						
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 0%	Total	` '	` '	SD 0%	
#Skin: Lipoma		1/50 (2%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Skin: Liposarcoma		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Skin: Neural Crest Tumor		0/50 (09/.)	4/50 (20/)			0/50 (00/)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

#Skin: Neurofibroma or Schwannoma benign 0/50 (0%) 0/50 (0%) Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Me #Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% Formall Incidence Total 0/100 (0%) Mean 0% Total 0/100 (0%) Mean 0% Neurofibrosarcoma or Schwannoma (malignant or NOS) Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0%	
Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% #Skin:	(0%)
Neurofibroma or Schwannoma benign	ean 0% SD 0%
Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% #Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50	(0%)
Neurofibrosarcoma or Schwannoma (malignant or NOS) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% #Skin:	ean 0% SD 0%
#Skin:	(0%)
	ean 0% SD 0%
Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS)	
	(0%) ean 0% SD 0%
#Skin: Sarcoma	
O/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 Overall Incidence Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean	(0%) ean 0% SD 0%
#Skin: Schwannoma Benign 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50	(0%)
	ean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

11. Way 2000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Skin: Schwannoma Malignan	t	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcino		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcino Basosquamous Tumor Overall Incidence			0/50 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Skin: Squamous Cell Papillor		1/50 (2%)	4/50 (8%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 4.24%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Skin: Squamous Cell Papillor	ma or Papillom	a 1/50 (2%)	4/50 (8%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	5/100 (5%)	Mean 5%	SD 4.24%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin:	na, Papilloma,							
Squamous Cell Papillor Carcinoma or Keratoac	anthoma	4/50 (8%)	7/50 (14%)			0/50 (0%)	1/50 (2%)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Skin: Squamous Cell Papilloma,	Papilloma,	or Keratoacanthoma 4/50 (8%)	7/50 (14%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 4.24%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Trichoepithelioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Sebaceous Gland: Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma			0(50 (00))			0/50 /00/	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Spinal Cord: Astrocytoma Benign	•••••	0/50 (09/)	0/50 (09/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

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	Male					Female			
#Spinal Cord: Astrocytoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Spinal Cord: Glioma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
*Spleen: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%	
*Spleen: Fibrous Histiocytoma		0/50 (00()	0/50 (09/)			0/50 (00/)	0/40 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	
*Spleen: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)		
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%	
*Spleen: Hemangiosarcoma		0/50 (09/)	4/50 (29/)			0/50 (/09/.)	0/40 (09/)		
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Spleen: Leiomyosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Spleen: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Leiomyosarcoma		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papillon	na Squamous 0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Stomach, Forestomach: Squamous Cell Papilloma			•••••		•••••	•••••		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:04/29/2009

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Stomach, Glandular: Lipoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Testes: Adenoma		42/50 (84%)	41/50 (82%)					
Overall Incidence	Total	83/100 (83%)	Mean 83%	SD 1.41%				
*Thymus: Sarcoma		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign								
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
*Thymus: Thymoma Malignant		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:04/29/2009

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Thymus: Thymoma NOS		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malignan	t, NOS	0/50 (0%)	0/49 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Thyroid Gland: C-Cell: Adenoma		3/50 (6%)	6/50 (12%)			4/50 (8%)	7/50 (14%)	
Overall Incidence	Total	9/100 (9%)	Mean 9%	SD 4.24%	Total	11/100 (11%)	Mean 11%	SD 4.24%
*Thyroid Gland: C-Cell: Carcinoma		4/50 (00)	0/50 (40/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		4/50 (8%)	8/50 (16%)		•••••	4/50 (8%)	7/50 (14%)	
Overall Incidence	Total	12/100 (12%)	Mean 12%	SD 5.66%	Total	11/100 (11%)	Mean 11%	SD 4.24%
*Thyroid Gland: Follicular Cell: Adenoma		0/50 (00)	2/22 (221)			2/22 (22)	(201)	
Overall Incidence	Total	3/50 (6%) 3/100 (3%)	0/50 (0%) Mean 3%	SD 4.24%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Thyroid Gland: Follicular Cell: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma		3/50 (6%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	3/100 (3%)	Mean 3%	SD 4.24%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Lipoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Paraganglioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma		0/50 (09/)	0/50 (09/)			0/50 (00/)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Tongue: Squamous Cell Carcinoma	a or Papillon	na Squamous 1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tooth: Adamantinoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma		0.70	0.70				(00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Urinary Bladder: Hemangiosarcoma	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		, ,				,		
*Urinary Bladder: Leiomyosarcoma		0/50 (00/)	0/50 (0%)			0/50 (0%)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Urinary Bladder: Papilloma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Adenoma						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Carcinoma							•••••	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Deciduoma Benign								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

	Male		Female
#Uterus: Hemangioma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
#Uterus: Hemangiosarcoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
#Uterus: Leiomyoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
#Uterus: Leiomyosarcoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
#Uterus: Polyp Stromal Overall Incidence	Total	,	13/50 (26%) Mean 22% SD 5.66%
#Uterus: Sarcoma Stromal Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2% SD 2.83%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Uterus: Sarcoma Stromal or Po	lyp Stromal					0/50 (400/)	45/50 (200/)	
Overall Incidence					Total	9/50 (18%) 24/100 (24%)	15/50 (30%) Mean 24%	SD 8.49%
#Uterus: Schwannoma Malignan	t					0/50 (00/)	0/50 (00/)	
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Polyp						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
#Vagina: Sarcoma						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Zymbal's Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

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Report Date:04/29/2009

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058812305 052000505 059501107	03/21/01 01/21/04 03/06/02	727 727 727	50 (3) 50 (3) 50 (3)	26(673) 30(679) 22(673)	509.7 498.5 510.3	Formamide Ginseng 5-(Hydroxymethyl)-2-furfural
				Fen	nale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058812305 052000505 059501107	03/20/01 01/22/04 03/07/02	730 728 728	50 (5) 50 (5) 50 (5)	38(703) 36(700) 31(679)	358.3 355.0 332.2	Formamide Ginseng 5-(Hydroxymethyl)-2-furfural

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 99

			Male		Female
#All Organs: Benign Tumors					
_		45/50 (90%)	49/50 (98%) 50/50 (100	9%) 43/50 (86%)	42/50 (84%) 46/50 (92%)
verall Incidence	Total	144/150 (96%)	Mean 96% SD 5.29%	Total 131/150 (87.33)	%) Mean 87.33% SD 4.16%
All Organs: Malignant Tumors					40/50 (200/) 46/50 (200/)
verall Incidence	Total	25/50 (50%) 86/150 (57.33%)	26/50 (52%) 35/50 (70% Mean 57.33% SD 11.02%	,	, , , , , , , , , , , , , , , , , , , ,
All Organs: Malignant and Benign Tu		48/50 (96%)	49/50 (98%) 50/50 (100		45/50 (90%) 48/50 (96%)
verall Incidence	Total	147/150 (98%)	Mean 98% SD 2%	Total 142/150 (94.67)	, ,
All Organs: Hemangioma		0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%)	Mean 0% SD 0%
All Organs: Hemangiosarcoma		2/22 (224)			
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
All Organs: Hemangiosarcoma or He					0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	,	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%)	iviean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
All Organs: Histiocytic Sarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	otal	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
\ll Organs: Leukemia: Erythrocytic					•••••			
verall Incidence To	otal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Leukemia: Lymphocytic, Monocy Undifferentiated	ytic, Moi		18/50 (36%)	29/50 (569/\		10/50 (20%)	6/50 /429/\	0/50 /499/
	otal	15/50 (30%) 61/150 (40.67%)	Mean 40.67%	28/50 (56%) SD 13.61%	Total	25/150 (16.67%)	6/50 (12%) Mean 16.67%	9/50 (18%) SD 4.16%
All Organs: Malignant Lymphoma: Histiocyti or Undifferentiated Cell Type		hocytic, Mixed, NOS,						
verall Incidence To	otal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Mesothelioma: Benign	•••••	0/50 (0%)	0/50 (0%)	0/50 (09/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence To	otal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Mesothelioma: Benign, Malignan					•••••			0/50 (00/)
	-1-1	2/50 (4%)	2/50 (4%)	2/50 (4%)	T-1-1	2/50 (4%)	0/50 (0%)	0/50 (0%)
verall Incidence To	otal	6/150 (4%)	Mean 4%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

			Male				Female	
#All Organs: Mesothelioma: Malignant		2/50 (4%)	2/50 (4%)	2/50 (4%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/150 (4%)	Mean 4%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
#All Organs: Osteoma		0/50 (00)	0/50 (00/)	0/50 (004)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#All Organs: Osteosarcoma	•••••	0/50 /00()	4/50 (00/)	0/50 (0%)		0/50 (00/)	0/50 /0%)	4/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#All Organs: Osteosarcoma or Osteoma		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Adrenal Cortex: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Adrenal Cortex: Carcinoma	•••••	4/50 /00()	0/50 (0%)	0/50 (0%)		0/50 (00/)	0/50 /0%)	0/50 /00/
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Vehicle: WATER

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Page: 102

Species: RATS

Imor Incidence for Selected Control An Route: GAVAGE Report Date:04/29/2009

Length of Study: CHRONIC

			Male				Female	
Adrenal Medulla: Ganglioneuroma								
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Medulla: Hemangioma		0/50 (00/)	0/50 (00/)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Medulla: Pheochromocytoma Benign		-/				- 4		
overall Incidence	Total	9/50 (18%) 18/150 (12%)	4/50 (8%) Mean 12%	5/50 (10%) SD 5.29%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
drenal Medulla: Pheochromocytoma Comple	x	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
drenal Medulla: Pheochromocytoma Maligna	ınt							
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Adrenal Medulla: Pheochromocytoma: Benign	, Comple		4/50 (00/)	5/50 (400)		0/50 (00)	4/50 (00)	0/50 (00)
overall Incidence	Total	9/50 (18%) 18/150 (12%)	4/50 (8%) Mean 12%	5/50 (10%) SD 5.29%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

11. Way 2000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 103

			Male				Female	
#Bone: Chondrosarcoma			2/22 (221)	2/22 (22)		2/52 (22)	2(7-2)	2/72 (221)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Chondrosarcoma or Chond	Iroma	0/50 /00/	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 /00/
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Chordoma		4/50 (00()	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma		0/50 (/0//)	4/50 (20/)	0/50 (09/)		0/50 (00/)	0/50 (0%)	4/50 (20()
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Bone: Osteosarcoma or Osteoma			(00)			(201)	0/20 (00)	(00)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 104 Report Date: 04/29/2009

Species: RATS Strain: F344 Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Brain: Astrocytoma Malignant Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Brain: Ependymoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Brain: Ependymoma Malignant Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Brain: Glioma Malignant Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Brain: Granular Cell Tumor Benig Overall Incidence	n Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
*Brain: Medulloblastoma Mal		0/50 (09/)	0/50 (0%)	0/50 (00/)		0/50 (00/)	0/50 (09/)	0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

11. Way 2000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 105

			Male				Female	
Brain: Meningioma Malignant		0/50 (00/)	0/50 (00)	0/50 (00/)		0(50 (00))	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Meningioma: Benign, Mali	gnant, NOS	0/50 (00/)	0/50 (00/)	0/50 (09/)		0/50 (00/)	0/50 (00/)	0/50 (09/)
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Oligodendroglioma Benigi	 1	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Malign	ant	2/20 (201)				(201)	(201)	0.50
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Oligodendroglioma, Gliom	a, or Astroc							
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Brain: Osteosarcoma		0/50 (00/)	0/50 (00)	0/50 (0%)		0/50 (00/)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male	Female
Brain: Schwannoma Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
Clitoral/Preputial Gland: Adenoma				
Overall Incidence	Total	1/50 (2%) 6/150 (4%)	0/50 (0%) 5/50 (10%) Mean 4% SD 5.29%	2/50 (4%) 1/50 (2%) 3/50 (6%) Total 6/150 (4%) Mean 4% SD 2%
Clitoral/Preputial Gland: Carcinoma				
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) 1/50 (2%) Mean 1.33% SD 1.15%	0/50 (0%) 1/50 (2%) 0/50 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15%
Clitoral/Preputial Gland: Carcinoma or Adenoma		2/50 (4%)	0/50 (0%) 6/50 (12%)	2/50 (4%) 2/50 (4%) 3/50 (6%)
Overall Incidence	Total	8/150 (5.33%)	Mean 5.33% SD 6.11%	Total 7/150 (4.67%) Mean 4.67% SD 1.15%
Clitoral/Preputial Gland: Fibrosarcoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
Clitoral/Preputial Gland: Sarcoma				0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 107

			Male				Female	
Clitoral/Preputial Gland: Squamous Cell Papilloma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Ear: Neural Crest Tumor	••••	0/50 (00/)	0/50 (00()	0/50 (00/)		0/50 (00)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Esophagus: Fibrosarcoma	••••	0/50 (00/)	0/50 (00%)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Esophagus: Lipoma		0/50 (00/)	0/50 (00()	0/50 (00/)			0/50 (00/)	0/50 (004)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Eye: Amelanotic Melanoma, Ben	ign							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Eye: Melanoma Malignant		0/50 (00/)	0/50 (00()	0/50 (00/)		0/50 (00)	4/50 (00/)	0/50 /00/
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Species: RATS Strain: F344 Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male	Female
#Eye: Schwannoma Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Harderian Gland: Carcinoma				0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
#Harderian Gland: Carcinoma or Adenoma		0/50 (00/)	4/50 (00) 0/50 (00)	0/50 (00) 0/50 (00) 0/50 (00)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Heart: Schwannoma Benign		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Heart: Schwannoma Malignant				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% SD 1.15%
#Intestine Large: Colon/Rectur Adenoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Intestine Large: Colon/Rectur Carcinoma	n:	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectur Carcinoma or Adenoma	n:	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Intestine Large: Colon/Rectur Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyoma		- /						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Intestine Small: Jejunum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

e: GAVAGF

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male	Female
Intestine Small: Jejunum: Granular Cell Tumor Maligr	nant			
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Small: Jejunum: Leiomyoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	,
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Small: Jejunum: Leiomyosarcoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	,
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Small: Site Unspecifi Carcinoma				
		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
erall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	6 Total 0/150 (0%) Mean 0% SD 0%
ntestine Small: Site Unspecifi Carcinoma or Adenoma	ied:			
		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Small: Site Unspecifi Granular Cell Tumor Maligr	ied:	0/50 (0%)	0/50 (0%) 0/50 (0%)	o) 0/50 (0%) 0/50 (0%) 0/50 (0%)
	Tatal	` ,	` ,	,
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Site Unspeci	fied:							
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Intestine Small: Site Unspeci Leiomyosarcoma	fied:	0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
	-	0/50 (0%)	0/50 (0%)	0/50 (0%)	+	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma		- 1		- 1				- ()
		2/50 (4%)	0/50 (0%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
*Islets, Pancreatic: Carcinoma				- / / / /				- ()
		1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma	•••••						•••••	
		3/50 (6%)	0/50 (0%)	4/50 (8%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 4.16%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
*Kidney: Pelvis and Transitior Carcinoma	nal Epitheliu	m:						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 112

Report Date: 04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma (0%)(0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% *Kidney: Pelvis and Transitional Epithelium: Papilloma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 0/50 (0%)SD 0% **Overall Incidence** 0/150 (0%) SD 0% Total Mean 0% Total 0/150 (0%)Mean 0% *Kidney: Renal Tubule: Adenoma 1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/150 (1.33%) Mean 1.33% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma (0%)(2%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 1/50 0/50 0/50 SD 1.15% **Overall Incidence** Total 1/150 (0.67%) Mean 0.67% Total 0/150 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma or Adenoma 0/50 1/50 (2%)2/50 (4%)(0%)0/50 0/50 0/50 (0%)**Overall Incidence** Total 3/150 (2%) Mean 2% SD 2% Total 0/150 Mean 0% SD 0% *Kidney: Renal Tubule: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/150 (0%) SD 0% 0/150 (0%) SD 0% Total Mean 0% Total Mean 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male		Female
*Kidney: Renal Tubule: Lipoma					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SD 09	(0%) 0/50 (0%) % Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Benign		0/50 (0%)	0/50 (0%) 0/50	(0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 09	` '	Mean 0% SD 0%
*Kidney: Renal Tubule: Nephroblastoma	•••••				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SD 09	(0%) 0/50 (0%) % Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Sarcoma		2/22 (221)			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SD 09	(0%) 0/50 (0%) % Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
*Liver: Cholangioma					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SD 09	(0%) 0/50 (0%) % Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
*Liver: Hemangiosarcoma		•••••			
•	Tatal	0/50 (0%)	` ,	(0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 09	% Total 0/150 (0%)	Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 114

			Male				Female	
Liver: Hepatocellular Adenor	ma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
iver: Hepatocellular Carcino	oma							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
iver: Hepatocellular Carcino	oma or Hepatob	lastoma						
	-	0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
iver: Hepatocellular Carcino	oma or Hepatoc		4/50 (20/)	0/50 (00/)		2/50 (40/)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%
		1/130 (0.07 /8)				, ,		3D 2.31/6
iver: Hepatocellular Carcino Hepatoblastoma	oma, Hepatocell	•						
		0/50 (0%)	1/50 (2%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
ung: Alveolar/Bronchiolar A	Adenoma	0/50 (/0//)	0/50 (00/)	0/50 (09/)		4/50 (20/)	1/50 (29/)	0/50 /09/ \
	Takel	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	1/50 (2%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male				Female	
Lung: Alveolar/Bronchiolar Ca	rcinoma	1/50 (2%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Lung: Alveolar/Bronchiolar Cal Adenoma	rcinoma or Al							
verall Incidence	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	2/50 (4%) 3/150 (2%)	1/50 (2%) Mean 2%	0/50 (0%) SD 2%
ung: Fibrosarcoma	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
ung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
ung: Sarcoma		0/50 (00/.)	0/50 (00/)	0/50 (0%)		0/50 (00/)	0/50 (0%)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
ung: Squamous Cell Carcinor	na	0/50 (00/.)	0/50 (09/)	0/50 (09/)		0/50 (00/)	0/50 (09/)	0/50 (09/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Page: 116 Report Date: 04/29/2009

Species: RATS Strain: F344 Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

	·		Male				Female	
#Lymph Node: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
			wican 070				ivican 070	
#Mammary Gland: Adenolipoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 /00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall moldenee		, ,				,		
#Mammary Gland: Adenoma								
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 4/150 (2.67%)	2/50 (4%) Mean 2.67%	2/50 (4%) SD 2.31%
Overall illicidence	I Olai	1/130 (0.07/8)	IVIEAIT 0.07 /6	30 1.13%	I Olai	4/130 (2.07/6)	ivieaii 2.07 /6	3D 2.31/0
#Mammary Gland: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	0/50 (0%) SD 2.31%
#Mammary Gland: Carcinoma or Adenoma								
Overall Incidence	Total	1/50 (2%)	0/50 (0%)	0/50 (0%) SD 1.15%	Total	2/50 (4%)	2/50 (4%)	2/50 (4%) SD 0%
Overali incidence	Total	1/150 (0.67%)	Mean 0.67%	1.15%	Total	6/150 (4%)	Mean 4%	3D 0%
#Mammary Gland: Fibroadenoma								
Occupation of the second	T-1-1	2/50 (4%)	2/50 (4%)	1/50 (2%)	T-1-1	33/50 (66%)	32/50 (64%)	29/50 (58%)
Overall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 1.15%	Total	94/150 (62.67%)	Mean 62.67%	SD 4.16%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 117

			Male				Female	
Mammary Gland: Fibroma								
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
Mammary Gland: Fibroma, Fibroadenoma	a or Adenoma							
overall Incidence	Total	4/50 (8%) 7/150 (4.67%)	2/50 (4%) Mean 4.67%	1/50 (2%) SD 3.06%	Total	33/50 (66%) 96/150 (64%)	33/50 (66%) Mean 64%	30/50 (60%) SD 3.46%
Mammary Gland: Fibroma, Fibroadenoma	a, Carcinoma, c	or Adenoma 4/50 (8%)	2/50 (4%)	1/50 (2%)		35/50 (70%)	33/50 (66%)	30/50 (60%)
overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 3.06%	Total	98/150 (65.33%)	Mean 65.33%	SD 5.03%
Mesentery: Fibrosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Mesentery: Hemangiosarcoma			(00)			0/20 (004)	(00)	. (201)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Mesentery: Lipoma		0/50 (00/)	0/50 (0%)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 118

			Male				Female	
Mesentery:								
Rhabdomyosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Nose: Adenoma		0.50	-(-()		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Nose:								
Chondroma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Nose:								
Squamous Cell Carcinom	а	0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	()	0/50 (0%) SD 0%
	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, To Papilloma Squamous or F	ongue, Phary							
i apilionia oqualilous oi i	аршоша	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
		` ,						
Oral Cavity (Oral Mucosa, To Squamous Cell Carcinom		nx, Tooth, Gingiva):						
- 4	· 	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or **Papilloma** (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% #Oral Mucosa: Squamous Cell Carcinoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% **#Oral Mucosa: Squamous Cell Papilloma** 0/50 0/50 (0%)(0%)0/50 (0%)SD 0% SD 0% Overall Incidence Total 0/150 (0%) Mean 0% Total 0/150 (0%) Mean 0% *Ovary: Cystadenoma 0/50 0/50 (0%)0/49 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% *Ovary: **Granulosa Cell Tumor Benign** (0%)0/49 (0%)SD 0% Overall Incidence Total 0/149 (0%) Mean 0% *Ovary: **Granulosa Cell Tumor Malignant** 0/50 (0%)(0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:04/29/2009

Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Ovary: Granulosa Cell Tumor:	Benign, Malign	ant, NOS				0/50 (0%)	0/50 (0%)	0/40 (0%)
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	Mean 0%	0/49 (0%) SD 0%
*Ovary: Granulosa-Theca Tumo	r Benign							0/40 /00/\
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Ovary: Granulosa-Theca Tumo	r Malignant					0/50 (00/)	0/50 (00/)	0/40 /00/\
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Ovary: Tubulostromal Adenom	na					0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence					Total	0/149 (0%)	Mean 0%	SD 0%
*Pancreas: Adenoma		0/50 (00/)	0/50 (00/)	4/50 (001)		0(50 (00))	0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pancreas: Carcinoma		0/50 /00()	0/50 (00/)	0/50 (00/)		0/50 (0%)	0/50 /00/	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 121

			Male				Female	
Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Pancreas: Mixed Tumor Benign		0/50 (00/)	0/50 (00/)	0/50 (09/)		0/50 (00/)	0/50 (00/)	0/50 (00()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Pancreas: Mixed Tumor Malignant		0/50 (00()	0/50 (00()	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00()
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Parathyroid Gland: Adenoma					•••••			
overall Incidence	Total	0/48 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/46 (0%) 0/142 (0%)	0/48 (0%) Mean 0%	0/48 (0%) SD 0%
Peripheral Nerve: Schwannoma Malignant		0/50 (00()	0/50 (00()	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Peripheral Nerve: Schwannoma: Benign, Mali	ignant, NOS		0/50 (004)	0/50 (00/)	•••••	0/50 (00)	0/50 (00)	0/50 (00/)
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Pituitary Gland: Pars Dista Adenoma	lis or Unspecif	ied Site:						
		11/50 (22%)	20/50 (40%)	15/50 (30%)		22/50 (44%)	16/50 (32%)	24/50 (48%)
verall Incidence	Total	46/150 (30.67%)	Mean 30.67%	SD 9.02%	Total	62/150 (41.33%)	Mean 41.33%	SD 8.33%
rituitary Gland: Pars Dista Carcinoma	lis or Unspecif	ied Site:						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%
Pituitary Gland: Pars Dista Carcinoma or Adenoma	lis or Unspecif						•••••	
		11/50 (22%)	20/50 (40%)	15/50 (30%)		24/50 (48%)	16/50 (32%)	25/50 (50%)
verall Incidence	Total	46/150 (30.67%)	Mean 30.67%	SD 9.02%	Total	65/150 (43.33%)	Mean 43.33%	SD 9.87%
Pituitary Gland: Pars Dista	lis or Unspecif	ied Site:						
Ganglioneuroma	•							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Interr Adenoma	nedia:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
rituitary Gland: Pars Interr Carcinoma	nedia:						•••••	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 123

			Male				Female		
*Pituitary Gland: Pars Intermed Carcinoma or Adenoma	dia:								
Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
*Prostate: Adenoma					•••••				
		0/50 (0%)	1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%					
*Prostate: Carcinoma or Adenoma									
		0/50 (0%)	1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%					
*Salivary Glands: Sarcoma					•••••				
		0/50 (0%)	0/50 (0%)	0/50 (0%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
#Seminal Vesicle: Adenoma		2(-2)	(201)	- ((((((((((
		0/50 (0%)	1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%					
#Skeletal Muscle: Fibrous Histiocytoma		0/50 /00/	0/50 /00/	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (0%)	
	.	0/50 (0%)	0/50 (0%)	0/50 (0%)	-	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female **#Skeletal Muscle:** Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% **#Skeletal Muscle:** Hemangiosarcoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 Mean 0% **#Skeletal Muscle:** Lipoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% **#Skeletal Muscle:** Rhabdomyosarcoma (0%)(0%)0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 0/50 Mean 0% **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) SD 0% **#Skeletal Muscle:** Rhabdomyosarcoma or Rhabdomyoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 Mean 0% SD 0% **#Skeletal Muscle:** Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/150 (0%) SD 0% 0/150 (0%) SD 0% Total Mean 0% Total Mean 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 125

			Male				Female	
Skin: Basal Cell Adenoma		1/50 (2%)	1/50 (2%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
Skin:								
Basal Cell Adenoma or	Basosquamou	s Tumor Benign	4/50 (00/)	4/50 (00/)		4/50 (00/)	4/50 (00/)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%
Skin: Basal Cell Adenoma, B Trichoepithelioma			1/50 (2%)	1/50 (2%)		2/50 (4%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	3/150 (2%)	Mean 2%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%
Skin: Basal Cell Carcinoma	•••••	2/22 (201)			•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin:								
Basal Cell Carcinoma o	or Basosquamo	us Tumor (malignant o	r					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma, Tumor (benign, malign:		Trichoepithelioma						
	-	1/50 (2%)	1/50 (2%)	1/50 (2%)	T	2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female			
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma 10/50 (20%) 2/50 (4%) 4/50 (8%) 4/50 (8%) 3/50 (6%) 0/50 (0%)										
Overall Incidence	Total	16/150 (10.67%)	2/50 (4%) Mean 10.67%	4/50 (8%) SD 8.33%	Total	7/150 (4.67%)	Mean 4.67%	0/50 (0%) SD 4.16%		
#Skin: Fibroma										
Overall Incidence	Total	6/50 (12%) 13/150 (8.67%)	2/50 (4%) Mean 8.67%	5/50 (10%) SD 4.16%	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%		
Skin: Fibroma, Fibrosarcoma, S Fibrous Histiocytoma										
Overall Incidence	Total	7/50 (14%) 16/150 (10.67%)	3/50 (6%) Mean 10.67%	6/50 (12%) SD 4.16%	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%		
Skin: Fibrosarcoma	•••••	0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%		
Skin: Fibrosarcoma, Sarcoma, Histiocytoma		,								
Overall Incidence	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Skin: Fibrous Histiocytoma	• • • • • • • • • • • • • • • • • • • •				•••••					
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

Page: 127 Report Date:04/29/2009

Species: RATS Strain: F344

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Skin: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma	•••••	8/50 (16%)	0/50 (0%)	2/50 (4%)	•••••	2/50 (4%)	2/50 //49/)	0/50 (09/)
Overall Incidence	Total	8/50 (16%) 10/150 (6.67%)	0/50 (0%) Mean 6.67%	2/50 (4%) SD 8.33%	Total	2/50 (4%) 4/150 (2.67%)	2/50 (4%) Mean 2.67%	0/50 (0%) SD 2.31%
#Skin: Lipoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma		0/50 (00()	0/50 (00/)	0/50 /00/)		0/50 (00/)	0/50 (00/)	0/50 (0)()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neural Crest Tumor		0/50 (00/)	0/50 (0%)	0/50 (0%)	•••••	0/50 (/0//)	0/50 (0%)	0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 128

			Male				Female	
Skin: Neural Crest Tumor, Maliç	gnant							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
						` '		
Skin: Neurofibroma or Schwani	noma benign							
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Neurofibrosarcoma or Sc	hwannoma (r	malignant or NOS)			•••••			
Neuronbrosarooma or oo	nwamoma (i	1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Skin: Neurofibrosarcoma, Neur malignant or NOS)	ofibroma, or	Schwannoma (benign,						
manghant of itoo,		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Skin: Sarcoma								
Normall In all Innas	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Schwannoma Benign		(201)					2(-2)	2/22 (221)
Wordl Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	3D 0%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 129

			Male				Female	
≮Skin: Schwannoma Malignant	:							
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
						` '		
Skin: Squamous Cell Carcino	ma							
N	T-1-1	0/50 (0%)	1/50 (2%)	1/50 (2%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Carcino Basosquamous Tumor (1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papillon		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
	Total	` ,	0/00 (0/0)	0/00 (0/0)		` '	` '	` '
verali incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Overall Incidence fSkin: Squamous Cell Papillon		a			Total			
Skin: Squamous Cell Papillon			Mean 0.67% 0/50 (0%) Mean 0.67%	SD 1.15% 0/50 (0%) SD 1.15%	Total Total	1/150 (0.67%) 0/50 (0%) 1/150 (0.67%)	Mean 0.67% 1/50 (2%) Mean 0.67%	O/50 (0%) SD 1.15%
Skin: Squamous Cell Papillon Overall Incidence	na or Papilloma Total na, Papilloma,	a 1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Skin: Squamous Cell Papilloma,	Papilloma,	or Keratoacanthoma 9/50 (18%)	0/50 (0%)	2/50 (4%)		2/50 (4%)	3/50 (6%)	0/50 (0%)
Overall Incidence	Total	11/150 (7.33%)	Mean 7.33%	SD 9.45%	Total	5/150 (3.33%)	Mean 3.33%	SD 3.06%
#Skin: Trichoepithelioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Sebaceous Gland: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (09/)	0/50 (00/)	0/50 (00/)	•••••	0/50 (00/)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Spinal Cord: Astrocytoma Benign					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 131

Report Date:04/29/2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

			Male				Female	
Spinal Cord: Astrocytoma Malignant		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 /00/	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Spinal Cord: Glioma Malignant	••••	0.70	2/22 (221)	0.770 (00.0)		(201)	(00)	2/22 (224)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Spleen: Fibrosarcoma								
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
pleen: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
pleen: Hemangioma	•••••							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Spleen: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 132

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Spleen: Leiomyosarcoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/30 (0%)	Mean 0%	SD 0%
*Spleen: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Leiomyosarcoma		0/50 (00/)	0/50 (00/)	0/50 /00/)		0/50 /00/	0/50 (00/)	0/50 (00())
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papillom		0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	4/50 (20/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Stomach, Forestomach: Squamous Cell Papilloma						•••••	•••••	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 133

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Stomach, Glandular: Lipoma	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Stomach, Glandular: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Testes: Adenoma		44/50 (88%)	45/50 (90%)	48/50 (96%)				
Overall Incidence	Total	137/150 (91.33%)	Mean 91.33%	SD 4.16%				
*Thymus: Sarcoma		0/49 (0%)	0/50 (0%)	0/48 (0%)		0/48 (0%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/147 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign		0/40 /00/	0/50 (0%)	0/49 (09/)		0/49 (00/)	0/49 (09/)	4/40 (20%)
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/48 (0%) 1/144 (0.69%)	0/48 (0%) Mean 0.69%	1/48 (2%) SD 1.2%
*Thymus: Thymoma Malignant								
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/48 (0%) 1/144 (0.69%)	1/48 (2%) Mean 0.69%	0/48 (0%) SD 1.2%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 134

Report Date:04/29/2009

Length of Study: CHRONIC

			Male	Female
*Thymus: Thymoma NOS		0/49 (0%)	0/50 (0%) 0/48 (0%)	0/48 (0%) 0/48 (0%) 0/48 (0%)
Overall Incidence	Total	0/147 (0%)	Mean 0% SD 0%	Total 0/144 (0%) Mean 0% SD 0%
*Thymus: Thymoma: Benign, Malignan	t, NOS	0/49 (0%)	0/50 (0%) 0/48 (0%)	0/48 (0%) 1/48 (2%) 1/48 (2%)
Overall Incidence	Total	0/147 (0%)	Mean 0% SD 0%	Total 2/144 (1.39%) Mean 1.39% SD 1.2%
*Thyroid Gland: C-Cell: Adenoma		0/50 (400/)	44/50 (000) 4/50 (00)	F/F0 (400))
Overall Incidence	Total	6/50 (12%) 18/150 (12%)	11/50 (22%) 1/50 (2%) Mean 12% SD 10%	5/50 (10%) 6/50 (12%) 11/50 (22%) Total 22/150 (14.67%) Mean 14.67% SD 6.43%
*Thyroid Gland: C-Cell: Carcinoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 4/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% SD 1.15%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma				
Overall Incidence	Total	6/50 (12%) 18/150 (12%)	11/50 (22%) 1/50 (2%) Mean 12% SD 10%	5/50 (10%) 6/50 (12%) 12/50 (24%) Total 23/150 (15.33%) Mean 15.33% SD 7.57%
*Thyroid Gland: Follicular Cell: Adenoma		0/50 (004)	0.50 (00)	
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) 1/50 (2%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 135

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Thyroid Gland: Follicular Cell: Carcinoma		1/50 (2%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma		4/50 (00()	4/50 (00)	2/50 (00/)		0/50 (0%)	0/50 (00/)	0/50 (40())
Overall Incidence	Total	1/50 (2%) 5/150 (3.33%)	1/50 (2%) Mean 3.33%	3/50 (6%) SD 2.31%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
#Tissue NOS: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Tissue NOS: Paraganglioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 136

			Male				Female						
FTongue: Squamous Cell Carcinoma or Papilloma Squamous													
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%					
fTongue: Squamous Cell Papilloma		0/50 (00/)	0/50 (09/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (0%)					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%					
Tooth: Adamantinoma Malignant		0/50 (00()	0/50 (00()	0/50 (0%)		0/50 (00/)	0/50 (00/)	0/50 (0%)					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%					
Tooth: Odontoma													
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%					
Jrinary Bladder: Carcinoma		0/50 (00()	0/50 (00()	0/50 (00/)	•••••	0/50 (00)	0/50 /00/	0/50 (0%)					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%					
Urinary Bladder: Carcinoma or Papilloma													
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%					

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Urinary Bladder: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Urinary Bladder: Leiomyosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		,				` ,		
*Urinary Bladder: Papilloma								
Overell Institutes	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Uterus:						•••••		
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma								
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%
	•••••							•••••
#Uterus: Deciduoma Benign						0/50 (00/)	0/50 (00/)	0/50 (09/)
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups **Route:** GAVAGE Page: 138

Report Date:04/29/2009

Contract/Lab: All Laboratories
Species: RATS

Species: RATS Strain: F344

Length of Study: CHRONIC

Vehicle: WATER

	Male			Female	
#Uterus: Hemangioma			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	1	Γotal	0/150 (0%)	Mean 0%	SD 0%
#Uterus: Hemangiosarcoma					
Overall Incidence	1	Γotal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Leiomyoma					
Overall Incidence	ı	Γotal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Leiomyosarcoma					
Overall Incidence	1	Γotal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Polyp Stromal			•••••		•••••
Overall Incidence	Т	Γotal	7/50 (14%) 23/150 (15.33%)	8/50 (16%) Mean 15.33%	8/50 (16%) SD 1.15%
#Uterus: Sarcoma Stromal		•••••			
Overall Incidence	ר	Γotal	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 139

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE Vehicle: WATER

			Male		Female				
#Uterus: Sarcoma Stromal or Polyp	Stromal								
Overall Incidence					Total	7/50 (14%) 23/150 (15.33%)	8/50 (16%) Mean 15.33%	8/50 (16%) SD 1.15%	
#Uterus: Schwannoma Malignant						4/50 (00/)	0/50 (00/)	0/50 (00/)	
Overall Incidence					Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	
#Vagina: Polyp				•••••					
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Vagina: Sarcoma									
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Zymbal's Gland: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Zymbal's Gland: Carcinoma		- (a)	0.000	0.000		(201)	(004)	2(72 (22))	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 140

Male							Female	
#Zymbal's Gland: Carcinoma or Adenoma		0/50 (00/)	0/50 (00/)	0/50 /00/\		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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Report Date:04/29/2009

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest	052001105 059601105 059901705 059700601 058800603 059700805 059302507	07/14/03 06/04/01 08/25/03 05/25/00 08/06/01 10/01/01 06/16/03	729 729 729 726 729 729 729	50 (5) 50 (5) 50 (5) 50 (5) 50 (5) 49 (5) 50 (5)	23(678) 26(676) 28(686) 32(693) 27(680) 27(683) 20(668)	526.9 540.9 525.6 529.7 537.2 525.0 536.2	1-Bromopropane Cumene Diethylamine Methyl isobutyl ketone alpha-Methylstyrene Propargyl alcohol Tetralin
				Fen	nale		
Battelle Northwest	052001105 059601105 059901705 059700601 058800603 059700805 059302507	07/14/03 06/04/01 08/25/03 05/25/00 08/06/01 10/01/01 06/16/03	730 731 730 727 730 730 730	50 (5) 50 (5) 50 (5) 50 (5) 50 (5) 50 (5) 50 (5)	34(702) 21(674) 31(687) 35(694) 27(647) 29(678) 31(682)	386.5 356.9 378.3 365.6 351.9 353.3 370.8	1-Bromopropane Cumene Diethylamine Methyl isobutyl ketone alpha-Methylstyrene Propargyl alcohol Tetralin

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups
Route: INHALATION

Page: 142 Report Date: 04/29/2009

Species: RATS Strain: F344

Vehicle: AIR

Length of Study: CHRONIC

			Male	Female
#All Organs: Benign Tumors				
		48/50 (96%) 50/50 (100%) 48/50 (96%)	48/50 (96%) 44/50 (88%) 48/50 (96%) 48/49 (98%)	45/50 (90%) 44/50 (88%) 43/50 (86%) 44/50 (88%) 43/50 (86%) 42/50 (84%) 40/50 (80%)
Overall Incidence	Total	334/349 (95.7%)	Mean 95.71% SD 3.72%	Total 301/350 (86%) Mean 86% SD 3.27%
#All Organs: Malignant Tumors				
•		38/50 (76%) 31/50 (62%) 33/50 (66%)	36/50 (72%) 31/50 (62%) 32/50 (64%) 32/49 (65%)	26/50 (52%) 24/50 (48%) 24/50 (48%) 22/50 (44%) 25/50 (50%) 26/50 (52%) 25/50 (50%)
Overall Incidence	Total	233/349 (66.76%)	Mean 66.76% SD 5.3%	Total 172/350 (49.14%) Mean 49.14% SD 2.79%
#All Organs: Malignant and Benign T				
		50/50 (100%) 50/50 (100%) 50/50 (100%)	50/50 (100%) 49/50 (98%) 50/50 (100%) 49/49 (100%)	49/50 (98%) 50/50 (100%) 48/50 (96%) 46/50 (92%) 46/50 (92%) 47/50 (94%) 46/50 (92%)
Overall Incidence	Total	348/349 (99.71%)	Mean 99.71% SD 0.76%	Total 332/350 (94.86%) Mean 94.86% SD 3.24%
#All Organs: Hemangioma				
-		0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29% SD 0.76%	Total 1/350 (0.29%) Mean 0.29% SD 0.76%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female					
#All Organs: Hemangiosarcoma												
		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%)				
Overall Incidence	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	2/350 (0.57%)	Mean 0.57%	SD 1.51%				
#All Organs: Hemangiosarcoma or Hen	nangioma											
• • • • • • • • • • • • • • • • • • •	3 .	0/50 (0%) 1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 2/50 (4%)				
Overall Incidence	Total	3/349 (0.86%)	Mean 0.86%	SD 1.07%	Total	3/350 (0.86%)	Mean 0.86%	SD 1.57%				
#All Organs: Histiocytic Sarcoma							•••••	•••••				
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 2/50 (4%) 2/50 (4%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	4/350 (1.14%)	Mean 1.14%	SD 1.95%				
#All Organs: Leukemia: Erythrocytic							•••••					
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female							
#All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated														
onamerentatea		29/50 (58%) 25/50 (50%) 25/50 (50%)	26/50 (52%) 26/50 (52%)	25/50 (50%) 21/49 (43%)		16/50 (32%) 14/50 (28%) 17/50 (34%)	12/50 (24%) 18/50 (36%)	15/50 (30%) 20/50 (40%)						
Overall Incidence	Total	177/349 (50.72%)	Mean 50.69%	SD 4.47%	Total	112/350 (32%)	Mean 32%	SD 5.29%						
#All Organs: Malignant Lymphoma: Hi or Undifferentiated Cell T		nphocytic, Mixed, NOS,	,											
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)						
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%						
#All Organs: Mesothelioma: Benign														
g		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)						
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%						
#All Organs: Mesothelioma: Benign, M	alignant NO:													
	angnam, No	0/50 (0%) 1/50 (2%) 0/50 (0%)	3/50 (6%) 0/50 (0%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)						
Overall Incidence	Total	5/349 (1.43%)	Mean 1.43%	SD 2.23%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%						

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Mesothelioma: Malignant								
-		0/50 (0%) 1/50 (2%) 0/50 (0%)	3/50 (6%) 0/50 (0%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	5/349 (1.43%)	Mean 1.43%	SD 2.23%	Total	0/350 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma	•••••				•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma					•••••			
		2/50 (4%) 0/50 (0%) 3/50 (6%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	6/349 (1.72%)	Mean 1.72%	SD 2.43%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
#All Organs: Osteosarcoma or Osteoma					•••••			
		2/50 (4%) 0/50 (0%) 3/50 (6%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	6/349 (1.72%)	Mean 1.72%	SD 2.43%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Adrenal Cortex:								
		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)		3/50 (6%) 0/50 (0%) 8/50 (16%)	0/50 (0%) 2/50 (4%)	4/50 (8%) 0/50 (0%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	17/350 (4.86%)	Mean 4.86%	SD 5.87%
*Adrenal Cortex: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Ganglioneuroma					•••••			
-		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Hemangioma								
-		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Species: RATS Strain: F344 Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
Adrenal Medulla:								
Pheochromocytoma Beni	gn	10/50 (200/)	7/50 (4.40/)	7/50 (4.40/)		0/50 (40/)	1/50 (20/)	0/50 (00/)
		10/50 (20%) 8/50 (16%)	7/50 (14%) 8/50 (16%)	7/50 (14%) 8/49 (16%)		2/50 (4%) 3/50 (6%)	1/50 (2%) 1/49 (2%)	0/50 (0%) 1/50 (2%)
		9/50 (18%)	0/30 (10/0)	0/49 (1070)		2/50 (4%)	1749 (270)	1/30 (2/0)
Overall Incidence	Total	57/349 (16.33%)	Mean 16.33%	SD 2.13%	Total	10/349 (2.87%)	Mean 2.86%	SD 1.95%
		` ,				,		
Adrenal Medulla:								
Pheochromocytoma Com	plex							
		1/50 (2%)	0/50 (0%)	2/50 (4%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
overall Incidence	Total	3/349 (0.86%)	Mean 0.86%	SD 1.57%	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%
Adrenal Medulla: Pheochromocytoma Malic	anant							
, ,	•	0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	2/50 (4%)	3/49 (6%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		4/50 (8%)				1/50 (2%)		
overall Incidence	Total	11/349 (3.15%)	Mean 3.16%	SD 3.04%	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%
Adrenal Medulla:				•••••		•••••	•••••	•••••
Pheochromocytoma: Ben	ian Complex	x Malignant NOS						
	.g, complex	11/50 (22%)	7/50 (14%)	10/50 (20%)		3/50 (6%)	3/50 (6%)	0/50 (0%)
		8/50 (16%)	10/50 (20%)	10/49 (20%)		3/50 (6%)	1/49 (2%)	1/50 (2%)
		12/50 (24%)	(== , 3)	3. 10 (=0.3)		3/50 (6%)	(=,=,	(=.0)
		12/30 (27/0)						

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Bone: Chondrosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Bone: Chondrosarcoma or Cho	ondroma							
ononarosarosma or one	, mar o ma	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Bone: Chordoma			•••••					
		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.58%	SD 0.99%	Total	0/350 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Bone: Osteosarcoma								
		1/50 (2%) 0/50 (0%) 3/50 (6%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	5/349 (1.43%)	Mean 1.43%	SD 2.23%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Bone: Osteosarcoma or Osteoma								
		1/50 (2%) 0/50 (0%) 3/50 (6%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	5/349 (1.43%)	Mean 1.43%	SD 2.23%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Brain: Astrocytoma Malignant								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Brain: Ependymoma Benign								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Brain: Ependymoma Malignant								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
*Brain: Glioma Malignant								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		1/50 (2%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	3/350 (0.86%)	Mean 0.86%	SD 1.07%
*Brain: Granular Cell Tumor Benig								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
*Brain: Medulloblastoma Mal	•••••							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Brain: Meningioma Malignant								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, Mal	lignant NOS				•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Benig					•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Malig	ınant				•••••			
	•	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Brain:								
Oligodendroglioma, Glior	na, or Astroc		0.770 (00.4)	0/=0 (00/)		. (=0 (00)	0/50 (404)	2(52)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	2/50 (4%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	` '	Maan 00/	SD 0%	Total	` '	Mean 1.43%	CD 4 00/
verali incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	5/350 (1.43%)	weari 1.43%	SD 1.9%
Brain: Osteosarcoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
verall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
Brain: Schwannoma Malignant	•••••							
3		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	, ,	, ,		0/50 (0%)	, ,	` ,
verall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma								
		4/50 (8%)	0/50 (0%)	0/50 (0%)		3/49 (6%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	3/49 (6%)		0/50 (0%)	0/50 (0%)	4/50 (8%)
		0/50 (0%)	` '	` ,		0/50 (0%)	` '	` '

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Strain: F344

i: May2009

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Clitoral/Preputial Gland:								
		2/50 (4%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	1/50 (2%) 0/49 (0%)		1/49 (2%) 1/50 (2%) 4/50 (8%)	2/50 (4%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	6/349 (1.72%)	Mean 1.71%	SD 1.8%	Total	9/349 (2.58%)	Mean 2.58%	SD 2.76%
Clitoral/Preputial Gland: Carcinoma or Adenoma					•••••			
		6/50 (12%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	1/50 (2%) 3/49 (6%)		4/49 (8%) 1/50 (2%) 4/50 (8%)	3/50 (6%) 1/50 (2%)	1/50 (2%) 4/50 (8%)
Overall Incidence	Total	13/349 (3.72%)	Mean 3.73%	SD 4.24%	Total	18/349 (5.16%)	Mean 5.17%	SD 3.05%
Clitoral/Preputial Gland: Fibrosarcoma					•••••	•••••		
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%
Clitoral/Preputial Gland: Sarcoma					•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Clitoral/Preputial Gland: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%
Ear: Neural Crest Tumor					•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.77%	Total	0/350 (0%)	Mean 0%	SD 0%
Esophagus: Fibrosarcoma					•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Esophagus: Lipoma					•••••			
•		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Eye: Amelanotic Melanoma, I	Benign							
,	J	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Eye: Melanoma Malignant					•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Eye: Schwannoma Malignant					•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Harderian Gland: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Harderian Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Benign								
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.77%	Total	0/350 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Malignant								
		0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectun Adenoma			•••••					
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

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			Male			Female				
#Intestine Large: Colon/Rectui Carcinoma	m:									
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%		
fintestine Large: Colon/Rectu Carcinoma or Adenoma										
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%		
Intestine Large: Colon/Rectu Hemangioma										
-		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%		
Intestine Small: Duodenum: Carcinoma										
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%		

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Intestine Small: Duodenu Leiomyoma	m:							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Granular Cell Tumor Ma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma								
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Intestine Small: Jejunum Leiomyosarcoma	:							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
fintestine Small: Site Uns Carcinoma	pecified:							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Intestine Small: Site Uns Carcinoma or Adenom	pecified:							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
fIntestine Small: Site Uns Granular Cell Tumor N								
	-	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

ce for Selected Control Animal Groups

Route: INHALATION

Vehicle: AIR

Length of Study: CHRONIC

			Male		Female	
Intestine Small: Site Unsp Leiomyoma	ecified:					
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (29 0/50 (0%) 0/49 (09		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	
verall Incidence	Total	1/349 (0.29%)	Mean 0.29% SD 0.76	(,	Mean 0% SD 0%	
ntestine Small: Site Unsp Leiomyosarcoma						
•		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (09) 0/50 (0%) 0/49 (09)	, , ,	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	,
verall Incidence	Total	0/349 (0%)	Mean 0% SD 0%	Total 0/350 (0%)	Mean 0% SD 0%	
slets, Pancreatic: Adenoma						
		0/50 (0%) 3/50 (6%) 3/50 (6%)	1/50 (2%) 6/50 (12 3/50 (6%) 4/49 (89	, , ,	1/50 (2%) 2/50 (4%) 3/50 (6%) 1/50 (2%)	,
verall Incidence	Total	20/349 (5.73%)	Mean 5.74% SD 3.92	% Total 7/350 (2%)	Mean 2% SD 2.31%	
slets, Pancreatic: Carcinoma						
		3/50 (6%) 4/50 (8%) 1/50 (2%)	2/50 (4%) 1/50 (29) 1/50 (2%) 5/49 (10)	%) 1/50 (2%) 0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	17/349 (4.87%)	Mean 4.89% SD 3.29	` ,	Mean 0.57% SD 0.98%	

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Islets, Pancreatic: Carcinoma or Adenoma								
		3/50 (6%) 7/50 (14%) 4/50 (8%)	3/50 (6%) 4/50 (8%)	7/50 (14%) 9/49 (18%)		1/50 (2%) 0/50 (0%) 0/50 (0%)	2/50 (4%) 3/50 (6%)	2/50 (4%) 1/50 (2%)
verall Incidence	Total	37/349 (10.6%)	Mean 10.62%	SD 4.82%	Total	9/350 (2.57%)	Mean 2.57%	SD 2.23%
Kidney: Pelvis and Transitio	onal Epitheliu	m:						
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/348 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transition Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/348 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transition	onal Epitheliu	m:			•••••			
•		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/348 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Kidney: Renal Tubule: Adenoma								
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	0/348 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/49 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	1/348 (0.29%)	Mean 0.29%	SD 0.77%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		1/50 (2%)	2/50 (4%)	0/50 (0%)		1/49 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	3/349 (0.86%)	Mean 0.86%	SD 1.57%	Total	1/348 (0.29%)	Mean 0.29%	SD 0.77%
Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/00 (0/0)				0/00 (0/0)		

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Kidney: Renal Tubule: Lipoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/348 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Mesenchymal Tumor Benigr	 1				•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/348 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Nephroblastoma	•••••							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/348 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/348 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Liver: Cholangioma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Liver: Hemangiosarcoma					•••••			
Ç		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Adenoma					•••••			
		0/50 (0%) 1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Liver: Hepatocellular Carcinoma					•••••			
•		2/50 (4%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/349 (0.86%)	Mean 0.86%	SD 1.58%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Liver:								
Hepatocellular Carcine	oma or Hepatobl		(201)	2/=2 (22/)		. (== (==:)	2/22 (22()	2 (= 2 (22))
		2/50 (4%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overell Insidence	Tatal	0/50 (0%)	Maar 0.000/	CD 4 500/	Tatal	0/50 (0%)	Mana 0 000/	CD 0.700/
Overall Incidence	Total	3/349 (0.86%)	Mean 0.86%	SD 1.58%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Liver:								
Hepatocellular Carcine	oma or Hepatoce							
		2/50 (4%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)				0/50 (0%)		
Overall Incidence	Total	5/349 (1.43%)	Mean 1.43%	SD 1.51%	Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%
Liver: Hepatocellular Carcine Hepatoblastoma	•	2/50 (4%) 1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)	Tatal	1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	5/349 (1.43%)	Mean 1.43%	SD 1.51%	Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%
Lung:								
			4/50 (00/)	0/50 (00/)		4/50 (00/)	0/50 (00/)	0/50 (00/)
Alveolar/Bronchiolar	Adenoma	0/=0 (404)				1/50 (2%)	0/50 (0%)	0/50 (0%)
	Adenoma	2/50 (4%)	1/50 (2%)	0/50 (0%)			` ,	
	Adenoma	0/50 (0%)	1/50 (2%) 0/50 (0%)	1/49 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
	Total				Total		` ,	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

i: May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

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Tumor Incidence for Selected Control Animal Groups

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			Male				Female	
Lung: Alveolar/Bronchiolar C	arcinoma							
		1/50 (2%) 0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	1/50 (2%) 0/49 (0%)		1/50 (2%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	4/349 (1.15%)	Mean 1.14%	SD 1.07%	Total	3/350 (0.86%)	Mean 0.86%	SD 1.07%
Lung: Alveolar/Bronchiolar C Adenoma				•••••			•••••	
		3/50 (6%) 0/50 (0%) 1/50 (2%)	2/50 (4%) 0/50 (0%)	1/50 (2%) 1/49 (2%)		2/50 (4%) 1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	8/349 (2.29%)	Mean 2.29%	SD 2.14%	Total	5/350 (1.43%)	Mean 1.43%	SD 1.51%
Lung: Fibrosarcoma	•••••					•••••	•••••	
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Lung: Hemangiosarcoma	•••••							
-		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Lung: Sarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Lung: Squamous Cell Carcinoma					•••••			
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenolipoma								•••••
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/49 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	3/50 (6%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.58%	SD 1.54%	Total	4/350 (1.14%)	Mean 1.14%	SD 2.27%
#Mammary Gland: Carcinoma								
		0/50 (0%)	2/50 (4%)	0/50 (0%)		4/50 (8%)	10/50 (20%)	9/50 (18%)
		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		5/50 (10%) 3/50 (6%)	3/50 (6%)	7/50 (14%)
Overall Incidence	Total	4/349 (1.15%)	Mean 1.14%	SD 1.95%	Total	41/350 (11.71%)	Mean 11.71%	SD 5.71%
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	2/50 (4%)	0/50 (0%)		4/50 (8%)	10/50 (20%)	10/50 (20%)
		2/50 (4%) 0/50 (0%)	0/50 (0%)	2/49 (4%)		5/50 (10%) 3/50 (6%)	3/50 (6%)	10/50 (20%)
Overall Incidence	Total	6/349 (1.72%)	Mean 1.73%	SD 2.15%	Total	45/350 (12.86%)	Mean 12.86%	SD 6.82%
#Mammary Gland: Fibroadenoma			•••••				•••••	
i isi saasiisiila		2/50 (4%)	0/50 (0%)	2/50 (4%)		25/50 (50%)	24/50 (48%)	27/50 (54%)
		2/50 (4%) 1/50 (2%)	1/50 (2%)	1/49 (2%)		22/50 (44%) 14/50 (28%)	22/50 (44%)	26/50 (52%)
Overall Incidence	Total	9/349 (2.58%)	Mean 2.58%	SD 1.51%	Total	160/350 (45.71%)	Mean 45.71%	SD 8.67%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Mammary Gland: Fibroma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenom	a or Adenoma				•••••			
,		2/50 (4%) 2/50 (4%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	2/50 (4%) 3/49 (6%)		25/50 (50%) 22/50 (44%) 14/50 (28%)	24/50 (48%) 22/50 (44%)	27/50 (54%) 28/50 (56%)
Overall Incidence	Total	11/349 (3.15%)	Mean 3.16%	SD 1.98%	Total	162/350 (46.29%)	Mean 46.29%	SD 9.27%
Mammary Gland: Fibroma, Fibroadenom					•••••			
		2/50 (4%) 4/50 (8%) 1/50 (2%)	2/50 (4%) 1/50 (2%)	2/50 (4%) 3/49 (6%)		27/50 (54%) 26/50 (52%) 16/50 (32%)	31/50 (62%) 24/50 (48%)	30/50 (60%) 31/50 (62%)
Overall Incidence	Total	15/349 (4.3%)	Mean 4.3%	SD 2.15%	Total	185/350 (52.86%)	Mean 52.86%	SD 10.64%
Mesentery: Fibrosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Mesentery: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Mesentery: Lipoma	• • • • • • • • • • • • • • • • • • • •				•••••			
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Mesentery: Rhabdomyosarcoma	•••••				•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
*Nose: Adenoma	• • • • • • • • • • • • • • • • • • • •				•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/348 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Nose: Chondroma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	1/348 (0.29%)	Mean 0.29%	SD 0.76%
*Nose: Squamous Cell Carcin	oma							
•		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)
Overell lesidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/348 (0%)	Mean 0%	SD 0%
Overali incidence	Total	0/340 (0/0)	WCarr 070	30 0%	Total	0/340 (070)	Mean 070	OD 070
	, Tongue, Phary					,		
#Oral Cavity (Oral Mucosa	, Tongue, Phary					,		
∜Oral Cavity (Oral Mucosa Papilloma Squamous o	, Tongue, Phary	7nx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
#Oral Cavity (Oral Mucosa Papilloma Squamous o Overall Incidence #Oral Cavity (Oral Mucosa	, Tongue, Phary or Papilloma Total , Tongue, Phary	7nx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/349 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/49 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/350 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
#Oral Cavity (Oral Mucosa Papilloma Squamous o Overall Incidence	, Tongue, Phary or Papilloma Total , Tongue, Phary	7nx, Tooth, Gingiva): 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/349 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/49 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/350 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

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Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female				
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma											
гаршоша		1/50 (2%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%			
#Oral Mucosa: Squamous Cell Carcinoma											
		1/50 (2%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	0/350 (0%)	Mean 0%	SD 0%			
Oral Mucosa: Squamous Cell Papilloma											
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%			
Ovary: Cystadenoma											
•						0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			
Overall Incidence					Total	0/350 (0%)	Mean 0%	SD 0%			

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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Male			Fem	ale		
Ovary:						
Granulosa Cell Tumor Benign		0/50 (0	0%) 0/50	(0%)	0/50	(0%)
			0%)	(0%)	0/50	(0%)
			0%)	(070)	0/30	(070)
overall Incidence	Total	0/350 (0%)	,	n 0%	SD	0%
			• • • • • • • • • • • • • • • • • • • •			
Ovary: Granulosa Cell Tumor Malignant						
Granulosa Cen Tullion Manighant		0/50 (0	0%) 0/50	(0%)	0/50	(0%)
			0%) 1/50	(2%)	0/50	(0%)
			0%)	(= / - /	0.00	(5,5)
Overall Incidence	Total	1/350 (0.29	9%) Mea	n 0.29%	SD	0.76%
Ovary:		•••••		•••••		
Granulosa Cell Tumor: Benign, Malignant, NOS						
			0%) 0/50	(0%)	0/50	(0%)
			0%) 1/50	(2%)	0/50	(0%)
		,	0%)			
overall Incidence	Total	1/350 (0.29	,	n 0.29%		0.76%
Ovary:						
Granulosa-Theca Tumor Benign		0/50 (0	0%) 0/50	(0%)	0/50	(0%)
			0%) 0/50 0%) 0/50	(0%)	0/50	(0%)
			0%) 0/30	(070)	0/30	(070)
overall Incidence	Total	0/350 (0%)	,	n 0%	SD	0%
		3,000 (070)	, 11100	5,0	2.5	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Ovary: Granulosa-Theca Tumo	or Malignant							
						2/50 (4%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence					Total	2/350 (0.57%)	Mean 0.57%	SD 1.51%
Ovary: Tubulostromal Adenor	 ma							
						0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence					Total	0/350 (0%)	Mean 0%	SD 0%
Pancreas: Adenoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: RATS

Strain: F344

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Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Pancreas: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)(0%)(0%)0/50 0/50 0/49 (0%)0/50 0/50 0/50 (0%)0/50 (0%)SD 0% SD 0% Overall Incidence Total 0/348 (0%) Mean 0% Total 0/350 (0%) Mean 0% *Pancreas: Mixed Tumor Benign 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 2/49 (4%)(0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/348 (0.57%) Mean 0.58% SD 1.54% Total 0/350 (0%) Mean 0% SD 0% *Pancreas: **Mixed Tumor Malignant** (0%)(0%)(0%)0/50 (0%)0/50 0/49 (0%)0/50 (0%)0/50 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%) SD 0% SD 0% **Overall Incidence** Total 0/348 (0%) Mean 0% Total 0/350 (0%) Mean 0% *Parathyroid Gland: Adenoma 0/46 (0%)0/45 (0%)0/48 (0%)0/47 (0%)0/49 (0%)1/43 (2%)(0%)(0%)0/49 0/47 (0%)0/46 (0%)0/43 (0%)0/49 (0%)(0%) 0/48 (0%)0/49 **Overall Incidence** Total 0/330 (0%) Mean 0% SD 0% Total 1/326 (0.31%) Mean 0.33% SD 0.88%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Peripheral Nerve: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign, Ma	alignant, NOS	S						
•	•	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distalis Adenoma								
		37/50 (74%) 35/50 (70%) 36/50 (72%)	36/50 (72%) 34/49 (69%)	31/50 (62%) 36/49 (73%)		35/50 (70%) 24/49 (49%) 36/49 (73%)	35/50 (70%) 35/50 (70%)	29/50 (58%) 30/50 (60%)
Overall Incidence	Total	245/348 (70.4%)	Mean 70.41%	SD 4.07%	Total	224/348 (64.37%)	Mean 64.35%	SD 8.89%
Pituitary Gland: Pars Distalis Carcinoma	or Unspecif	ied Site:			•••••			
		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/49 (0%) 0/49 (0%)	1/50 (2%) 0/50 (0%)	2/50 (4%) 0/50 (0%)
Overall Incidence	Total	1/348 (0.29%)	Mean 0.29%	SD 0.76%	Total	3/348 (0.86%)	Mean 0.86%	SD 1.57%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Pituitary Gland: Pars Dista Carcinoma or Adenoma		ied Site:						
		37/50 (74%) 35/50 (70%) 37/50 (74%)	36/50 (72%) 34/49 (69%)	31/50 (62%) 36/49 (73%)		35/50 (70%) 24/49 (49%) 36/49 (73%)	36/50 (72%) 35/50 (70%)	31/50 (62%) 30/50 (60%)
verall Incidence	Total	246/348 (70.69%)	Mean 70.69%	SD 4.26%	Total	227/348 (65.23%)	Mean 65.21%	SD 8.77%
Pituitary Gland: Pars Dista Ganglioneuroma	lis or Unspecif	ied Site:	•••••					
Č		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	1/50 (2%) 0/49 (0%)		0/50 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/348 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/348 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Interr Adenoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/348 (0.29%)	Mean 0.29%	SD 0.77%	Total	0/348 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Interr Carcinoma	nedia:				•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/348 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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		Male				Female	
edia:							
	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Total	1/348 (0.29%)	Mean 0.29%	SD 0.77%	Total	0/348 (0%)	Mean 0%	SD 0%
	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)				
Total	0/349 (0%)	Mean 0%	SD 0%				
	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)				
Total	0/349 (0%)	Mean 0%	SD 0%				
	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
	Total Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/348 (0.29%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/349 (0%) Total 0/349 (0%) Total 0/349 (0%)	O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Mean 0.29% O/50 (0%)	O/50 (0%) 0/50 (0%) 1/49 (0%) 1/49 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/49 (2%) 0/50 (0%) 1/348 (0.29%) Mean 0.29% SD 0.77% O/50 (0%) 0/50 (0%)	O/50 (0%) 0/50 (0%) 0/49 (0%) 1/49 (2%) 0/50 (0%) 0/49 (0%) 1/49 (2%) 0/50 (0%) Total 1/348 (0.29%) Mean 0.29% SD 0.77% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) SD 0% Total 0/349 (0%) Mean 0% SD 0% 0/50 (0%) 0/49 (0%)	O/50 (0%)	Addia: 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/49 (2%) 0/50 (0%) 0/50 (

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Seminal Vesicle: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)				
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Fibrous Histiocytoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangioma								•••••
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/30 (0/8)				0/30 (0/0)		

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: F344 Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 180

			Male				Female	
#Skeletal Muscle: Lipoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma								
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Skeletal Muscle: Rhabdomyosarcoma or								
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Skeletal Muscle: Sarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

OII. May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin:								
Basal Cell Adenoma		0/50 (00/)	1/FO (20/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		1/50 (2%)	1/30 (2/0)	1743 (270)		0/50 (0%)	0/30 (0/0)	0/30 (0/0)
Overall Incidence	Total	4/349 (1.15%)	Mean 1.15%	SD 1.07%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma or	Basosquamous	s Tumor Benign						
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)		05		0/50 (0%)		05.00/
Overall Incidence	Total	4/349 (1.15%)	Mean 1.15%	SD 1.07%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin:								
Basal Cell Adenoma, B Trichoepithelioma		0/50 (0%) 0/50 (0%) 1/50 (2%)	1/50 (2%) 1/50 (2%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Trichoepithelioma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/50 (2%) 4/349 (1.15%)	1/50 (2%) Mean 1.15%	1/49 (2%) SD 1.07%	Total	0/50 (0%) 0/50 (0%) 1/350 (0.29%)	0/50 (0%) Mean 0.29%	1/50 (2%) SD 0.76%
Trichoepithelioma Overall Incidence #Skin:	Total	0/50 (0%) 0/50 (0%) 1/50 (2%) 4/349 (1.15%)	1/50 (2%) Mean 1.15%	1/49 (2%) SD 1.07%		0/50 (0%) 0/50 (0%) 1/350 (0.29%)	0/50 (0%) Mean 0.29%	1/50 (2%) SD 0.76%
Trichoepithelioma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/50 (2%) 4/349 (1.15%)	1/50 (2%) Mean 1.15%	1/49 (2%) SD 1.07%		0/50 (0%) 0/50 (0%) 1/350 (0.29%)	0/50 (0%) Mean 0.29%	1/50 (2%) SD 0.76%
Trichoepithelioma Overall Incidence #Skin:	Total	0/50 (0%) 0/50 (0%) 1/50 (2%) 4/349 (1.15%)	1/50 (2%) Mean 1.15%	1/49 (2%) SD 1.07%		0/50 (0%) 0/50 (0%) 1/350 (0.29%)	0/50 (0%) Mean 0.29%	1/50 (2%) SD 0.76%
Trichoepithelioma Overall Incidence #Skin:	Total	0/50 (0%) 0/50 (0%) 1/50 (2%) 4/349 (1.15%)	1/50 (2%) Mean 1.15% 0/50 (0%)	1/49 (2%) SD 1.07%		0/50 (0%) 0/50 (0%) 1/350 (0.29%) 0/50 (0%)	0/50 (0%) Mean 0.29% 0/50 (0%)	1/50 (2%) SD 0.76%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 0/50 (0%)1/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)3/50 (6%)0/50 (0%)**Overall Incidence** Total 4/349 (1.15%) Mean 1.14% SD 2.27% Total 0/350 (0%) Mean 0% SD 0% #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 (2%)0/50 (0%)0/50 (0%)(0%)1/50 (2%)1/50 (0%)0/50 0/50 (0%)1/50 (2%)1/49 (2%)0/50 (0%)0/50 (0%)1/50 (2%)4/50 (8%)0/50 (0%)**Overall Incidence** 8/349 (2.29%) SD 2.69% 1/350 (0.29%) SD 0.76% Total Mean 2.29% Total Mean 0.29% #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq. Papilloma, Keratoacanthoma, Trichoepithelioma (2%)(2%)(10%)1/50 0/50 (0%)1/50 5/50 1/50 0/50 (0%)2/50 (4%) (10%)0/50 (0%)0/50 (0%)1/50 (2%)5/50 (10%)(2%)1/50 **Overall Incidence** Total 19/349 (5.44%)Mean 5.46% SD 4.46% Total 4/350 (1.14%) Mean 1.14% SD 1.07% #Skin: **Fibroma** (6%)3/50 3/50 (6%)1/50 (2%)2/50 (4%)0/50 (0%)1/50 (2%)4/50 (8%)4/50 (8%)3/49 (6%)0/50 (0%)1/50 (2%)(2%)1/50 3/50 (6%)0/50 (0%)21/349 (6.02%) **Overall Incidence** Total Mean 6.02% SD 2% Total 5/350 (1.43%) Mean 1.43% SD 1.51%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Fibroma, Fibrosarcoma, Fibrous Histiocytoma	Sarcoma, Myx	koma, Myxosarcoma, o	·					
		3/50 (6%) 5/50 (10%) 6/50 (12%)	3/50 (6%) 5/50 (10%)	2/50 (4%) 4/49 (8%)		2/50 (4%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	1/50 (2%) 2/50 (4%)
Overall Incidence	Total	28/349 (8.02%)	Mean 8.02%	SD 2.83%	Total	7/350 (2%)	Mean 2%	SD 1.63%
#Skin: Fibrosarcoma								
		0/50 (0%) 1/50 (2%) 3/50 (6%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	6/349 (1.72%)	Mean 1.72%	SD 2.14%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
∜Skin: Fibrosarcoma, Sarcoma, Histiocytoma	Myxosarcom	a, or Fibrous						
		0/50 (0%) 1/50 (2%) 3/50 (6%)	0/50 (0%) 1/50 (2%)	1/50 (2%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	7/349 (2.01%)	Mean 2.01%	SD 2%	Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%
Skin: Fibrous Histiocytoma								
• • •		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Hemangioma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma								
·		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma								
		0/50 (0%) 0/50 (0%) 1/50 (2%)	4/50 (8%) 1/50 (2%)	0/50 (0%) 4/49 (8%)		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	10/349 (2.87%)	Mean 2.88%	SD 3.66%	Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%
#Skin: Lipoma								
·		2/50 (4%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 2/49 (4%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	5/349 (1.43%)	Mean 1.44%	SD 1.92%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male		Female	
#Skin: Liposarcoma						
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%) 0/50	(0%) (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0% SD 0%	Total 0/350 (0%)	Mean 0% SD	0%
#Skin: Neural Crest Tumor						
		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%)	1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%) 0/50	(0%) (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29% SD 0.76%	Total 1/350 (0.29%)	Mean 0.29% SD	0.76%
#Skin: Neural Crest Tumor, Ma						
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%) 0/50	(0%) (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0% SD 0%	Total 0/350 (0%)	Mean 0% SD	0%
#Skin: Neurofibroma or Schwa						
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%) 0/50	(0%) (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0% SD 0%	Total 0/350 (0%)	Mean 0% SD	0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

11. Way 2000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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-			Male			Female	
#Skin: Neurofibrosarcoma or Sc	chwannoma (ı	,	0/50 (00/)	0/50 (00/)	0/50 (00	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)	0/50 (0% 0/50 (0% 0/50 (0%	6) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.58%	SD 0.99%	Total 0/350 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Neurofibrosarcoma, Neurofibrosarcoma							
g		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)	0/50 (0% 0/50 (0% 0/50 (0%	6) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.58%	SD 0.99%	Total 0/350 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma	•••••						
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0% 0/50 (0% 0/50 (0%	6) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total 0/350 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Benign				•••••			
-		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0% 0/50 (0% 0/50 (0%	6) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total 0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

11. May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Schwannoma Malignant								
-		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.58%	SD 0.99%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin:					• • • • • • • • • • • • • • • • • • • •			
Squamous Cell Carcinom	na							
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Tatal	0/50 (0%)	Maar 0 000/	CD 0.700/	Total	1/50 (2%) 1/350 (0.29%)	Mean 0.29%	CD 0.700/
Overali incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	10121	1/300 (0.29%)	iviean 0.29%	SD 0.76%
	na, Basal Cell	Carcinoma,	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
#Skin: Squamous Cell Carcinom Basosquamous Tumor (n	na, Basal Cell	Carcinoma, NOS), or Carcinoma 1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)	Total	0/50 (0%) 0/50 (0%)	0/50 (0%)	
#Skin: Squamous Cell Carcinom Basosquamous Tumor (n Overall Incidence	na, Basal Cell nalignant or N	Carcinoma, NOS), or Carcinoma 1/50 (2%) 0/50 (0%) 3/50 (6%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
#Skin: Squamous Cell Carcinom Basosquamous Tumor (n Overall Incidence	na, Basal Cell nalignant or N Total	Carcinoma, NOS), or Carcinoma 1/50 (2%) 0/50 (0%) 3/50 (6%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
#Skin: Squamous Cell Carcinom Basosquamous Tumor (n Overall Incidence #Skin:	na, Basal Cell nalignant or N Total	Carcinoma, NOS), or Carcinoma 1/50 (2%) 0/50 (0%) 3/50 (6%) 5/349 (1.43%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%) 1/350 (0.29%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
#Skin: Squamous Cell Carcinom Basosquamous Tumor (n Overall Incidence #Skin:	na, Basal Cell nalignant or N Total	Carcinoma, NOS), or Carcinoma 1/50 (2%) 0/50 (0%) 3/50 (6%) 5/349 (1.43%)	0/50 (0%) 0/50 (0%) Mean 1.43%	1/50 (2%) 0/49 (0%) SD 2.23%		0/50 (0%) 0/50 (0%) 1/50 (2%) 1/350 (0.29%)	0/50 (0%) 0/50 (0%) Mean 0.29% 0/50 (0%)	0/50 (0%) SD 0.76%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

1: May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

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Report Date: 04/29/2009

Mean 0.29%

SD 0.76%

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Male Female #Skin: Squamous Cell Papilloma or Papilloma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/350 (0%) SD 0% Overall Incidence Total 0/349 (0%)Mean 0% SD 0% Total Mean 0% Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma (2%)1/50 (2%)4/50 (8%)0/50 (0%)1/50 0/50 (0%)1/50 0/50 (0%)(2%)(8%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 1/50 (2%)1/50 (2%)**Overall Incidence** Total 11/349 (3.15%)Mean 3.17% SD 3.48% Total 3/350 (0.86%)Mean 0.86% SD 1.07% Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 4/50 (8%)0/50 (0%)1/50 0/50 (0%)1/50 (2%)0/50 (0%)(2%)0/50 (0%)1/50 (2%)(8%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 10/349 (2.87%) Mean 2.88% SD 3.66% Total 2/350 (0.57%) Mean 0.57% SD 0.98% #Skin: Trichoepithelioma (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%) (0%) (2%) 0/50 (0%)0/50 1/50 (0%) 0/50 (0%)0/50

SD 0%

Total

1/350 (0.29%)

Total

0/349 (0%)

Mean 0%

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%) 1/50 (2%) 2/50 (4%)	1/50 (2%) 0/50 (0%)	1/50 (2%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	6/349 (1.72%)	Mean 1.72%	SD 1.38%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 1/50 (2%) 2/50 (4%)	1/50 (2%) 0/50 (0%)	1/50 (2%) 1/49 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	6/349 (1.72%)	Mean 1.72%	SD 1.38%	Total	0/350 (0%)	Mean 0%	SD 0%
Spinal Cord: Astrocytoma Benign								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Spinal Cord: Astrocytoma Malignant								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Spinal Cord: Glioma Malignant	•••••							
-		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Spleen: Fibrosarcoma	•••••							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Spleen: Fibrous Histiocytoma								
ŕ		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Spleen: Hemangioma								
		0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma	•••••				•••••			
•		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Spleen: Leiomyosarcoma					•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
Spleen: Sarcoma	•••••				•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinom	a							
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Stomach, Forestomach:								•••••
Squamous Cell Carcinom	a or Papillon	na Squamous 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date:04/29/2009

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			Male				Female	
#Stomach, Glandular: Lipoma								
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Stomach, Glandular:			•••••	•••••				
Sarcoma		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
*Testes: Adenoma								
		34/50 (68%) 42/50 (84%) 29/50 (58%)	36/50 (72%) 33/50 (66%)	35/50 (70%) 38/49 (78%)				
Overall Incidence	Total	247/349 (70.77%)	Mean 70.79%	SD 8.33%				
*Thymus: Sarcoma								
		0/43 (0%) 0/49 (0%) 0/47 (0%)	0/49 (0%) 0/42 (0%)	0/44 (0%) 0/47 (0%)		0/46 (0%) 0/47 (0%) 0/44 (0%)	0/48 (0%) 0/50 (0%)	0/48 (0%) 0/46 (0%)
Overall Incidence	Total	0/321 (0%)	Mean 0%	SD 0%	Total	0/329 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: RATS Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: AIR

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			Male				Female	
*Thymus: Thymoma Benign								
,		0/43 (0%) 0/49 (0%) 0/47 (0%)	0/49 (0%) 0/42 (0%)	0/44 (0%) 1/47 (2%)		1/46 (2%) 0/47 (0%) 0/44 (0%)	0/48 (0%) 1/50 (2%)	0/48 (0%) 0/46 (0%)
Overall Incidence	Total	1/321 (0.31%)	Mean 0.3%	SD 0.8%	Total	2/329 (0.61%)	Mean 0.6%	SD 1.02%
*Thymus: Thymoma Malignant	•••••				•••••			
, -		0/43 (0%) 0/49 (0%) 0/47 (0%)	0/49 (0%) 0/42 (0%)	0/44 (0%) 0/47 (0%)		0/46 (0%) 0/47 (0%) 0/44 (0%)	0/48 (0%) 0/50 (0%)	0/48 (0%) 0/46 (0%)
Overall Incidence	Total	0/321 (0%)	Mean 0%	SD 0%	Total	0/329 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma NOS	•••••				•••••			
		0/43 (0%) 0/49 (0%) 0/47 (0%)	0/49 (0%) 0/42 (0%)	0/44 (0%) 0/47 (0%)		0/46 (0%) 0/47 (0%) 0/44 (0%)	0/48 (0%) 0/50 (0%)	1/48 (2%) 0/46 (0%)
Overall Incidence	Total	0/321 (0%)	Mean 0%	SD 0%	Total	1/329 (0.3%)	Mean 0.3%	SD 0.79%
*Thymus: Thymoma: Benign, Malign	ant, NOS				•••••			
, , ,		0/43 (0%) 0/49 (0%) 0/47 (0%)	0/49 (0%) 0/42 (0%)	0/44 (0%) 1/47 (2%)		1/46 (2%) 0/47 (0%) 0/44 (0%)	0/48 (0%) 1/50 (2%)	1/48 (2%) 0/46 (0%)
Overall Incidence	Total	1/321 (0.31%)	Mean 0.3%	SD 0.8%	Total	3/329 (0.91%)	Mean 0.89%	SD 1.12%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male	Female
*Thyroid Gland: C-Cell: Adenoma				
		5/50 (10%) 1/50 (2%) 5/50 (10%)	3/50 (6%) 7/50 (14%) 3/49 (6%) 4/49 (8%)	3/50 (6%) 3/50 (6%) 4/50 (8%) 3/50 (6%) 2/50 (4%) 3/50 (6%) 3/50 (6%)
Overall Incidence	Total	28/348 (8.05%)	Mean 8.04% SD 3.82%	Total 21/350 (6%) Mean 6% SD 1.15%
*Thyroid Gland: C-Cell: Carcinoma	•••••			
		4/50 (8%) 2/50 (4%) 2/50 (4%)	1/50 (2%) 1/50 (2%) 0/49 (0%) 3/49 (6%)	1/50 (2%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 1/50 (2%) 2/50 (4%) 0/50 (0%)
Overall Incidence	Total	13/348 (3.74%)	Mean 3.73% SD 2.71%	Total 5/350 (1.43%) Mean 1.43% SD 1.51%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma	•••••			
		9/50 (18%) 3/50 (6%) 6/50 (12%)	3/50 (6%) 8/50 (16%) 3/49 (6%) 7/49 (14%)	4/50 (8%) 3/50 (6%) 4/50 (8%) 4/50 (8%) 3/50 (6%) 5/50 (10%) 3/50 (6%)
Overall Incidence	Total	39/348 (11.21%)	Mean 11.2% SD 5.15%	Total 26/350 (7.43%) Mean 7.43% SD 1.51%
*Thyroid Gland: Follicular Cell: Adenoma				
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/348 (0.29%)	Mean 0.29% SD 0.77%	Total 1/350 (0.29%) Mean 0.29% SD 0.76%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Thyroid Gland: Follicular Cell: Carcinoma								
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%) 0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/348 (0.86%)	Mean 0.86%	SD 1.57%	Total	0/350 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma					•••••			
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%) 0/50 (0%)	0/49 (0%)	1/49 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/348 (1.15%)	Mean 1.15%	SD 1.58%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Tissue NOS: Lipoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.77%	Total	0/350 (0%)	Mean 0%	SD 0%
#Tissue NOS: Paraganglioma							•••••	•••••
.		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/30 (0/0)	0/49 (0/0)		0/50 (0%)	0/30 (0/0)	0/30 (0/0)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Tissue NOS: Schwannoma Malignant								
_		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinom	a							
.,		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
#Tongue:								
Squamous Cell Carcinom	a or Papillon	na Squamous 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
fTongue: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Tooth: Adamantinoma Malignant								
		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/349 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Carcinoma or Papilloma			•••••					
·		0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	0/349 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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Report Date: 04/29/2009

Length of Study: CHRONIC

Male **Female** *Urinary Bladder: Hemangiosarcoma 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 0/49 0/49 (0%)0/50 0/50 (0%)**Overall Incidence** (0.29%)Mean 0.29% SD 0.76% 0/349 (0%) SD 0% Total 1/349 Total Mean 0% *Urinary Bladder: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(0%)(0%) 0/50 0/50 (0%)(0%)0/50 0/50 (0%)0/49 (0%)0/49 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/349 (0%) Mean 0% SD 0% Total 1/349 (0.29%) Mean 0.29% SD 0.76% *Urinary Bladder: Papilloma 0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 1/50 (2%)(0%)1/50 (2%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%) SD 0% Overall Incidence Total 2/349 (0.57%)Mean 0.57% SD 0.98% Total 0/349 (0%) Mean 0% #Uterus: Adenoma 0/50 (0%)0/50 (0%)1/50 (2%)(0%)0/50 0/50 (0%)0/50 (0%)(2%) 1/50 **Overall Incidence** Total 2/350 (0.57%) Mean 0.57% SD 0.98%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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Male			Female	
#Uterus: Carcinoma				
		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
#Uterus: Deciduoma Benign				
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%
eUterus: Hemangioma	•••••			
Hemangionia		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
#Uterus: Hemangiosarcoma				
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

1. Way2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 201

	Male			Female	
tUterus: Leiomyoma					
			0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence		Total	0/350 (0%)	Mean 0%	SD 0%
Uterus: Leiomyosarcoma		•••••			
			0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence		Total	0/350 (0%)	Mean 0%	SD 0%
Uterus: Polyp Stromal					
r diyp stroma			8/50 (16%) 12/50 (24%) 6/50 (12%)	13/50 (26%) 6/50 (12%)	8/50 (16%) 12/50 (24%)
Overall Incidence		Total	65/350 (18.57%)	Mean 18.57%	SD 5.97%
eUterus: Sarcoma Stromal					
			2/50 (4%) 1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence		Total	4/350 (1.14%)	Mean 1.14%	SD 1.57%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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Male			Female	
Uterus: Sarcoma Stromal or Polyp Stromal				
		10/50 (20%) 13/50 (26%) 6/50 (12%)	14/50 (28%) 6/50 (12%)	8/50 (16%) 12/50 (24%)
verall Incidence	Total	69/350 (19.71%)	Mean 19.71%	SD 6.58%
Jterus: Schwannoma Malignant				
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%
/agina: Polyp				
		0/50 (0%) 0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	2/350 (0.57%)	Mean 0.57%	SD 1.51%
/agina: Sarcoma	•••••			
Carconia		1/50 (2%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		5,55 (576)		

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Zymbal's Gland: Adenoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
₹Zymbal's Gland: Carcinoma					•••••			
		0/50 (0%) 1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		1/50 (2%) 0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/349 (0.57%)	Mean 0.57%	SD 0.98%	Total	3/350 (0.86%)	Mean 0.86%	SD 1.07%
Zymbal's Gland: Carcinoma or Adenoma					•••••			
		0/50 (0%) 1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%) 0/49 (0%)		1/50 (2%) 0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/349 (0.86%)	Mean 0.86%	SD 1.07%	Total	3/350 (0.86%)	Mean 0.86%	SD 1.07%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 204

Report Date:04/29/2009

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute Southern Research Institute	059902703 050517405 059900705 059201305 052000803	08/12/02 08/05/02 04/21/03 01/20/00 03/04/03	729 729 729 729 730 729	50 (3) 50 (3) 50 (3) 50 (3) 50 (3)	37(705) 33(703) 33(679) 31(702) 36(704)	452.8 510.0 460.9 448.0 452.1	Chromium picolinate monohydrate Cresols Goldenseal root powder 4-Methylimidazole Milk thistle extract
				Fen	nale		
Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute Southern Research Institute	059902703 050517405 059900705 059201305 052000803	08/12/02 N/A 04/21/03 01/20/00 03/04/03	733 N/A 731 735 732	50 (5) 0 (0) 50 (5) 50 (5) 50 (5)	36(702) 0(0) 30(699) 40(702) 38(693)	314.7 N/A 326.0 311.3 328.4	Chromium picolinate monohydrate Cresols Goldenseal root powder 4-Methylimidazole Milk thistle extract

: May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 205

			Male				Female	
All Organs: Benign Tumors								
3		49/50 (98%) 50/50 (100%)	50/50 (100%) 50/50 (100%)	47/50 (94%)		45/50 (90%) 48/50 (96%)	39/50 (78%)	46/50 (92%)
verall Incidence	Total	246/250 (98.4%)	Mean 98.4%	SD 2.61%	Total	178/200 (89%)	Mean 89%	SD 7.75%
All Organs: Malignant Tumors							•••••	
		27/50 (54%) 22/50 (44%)	23/50 (46%) 26/50 (52%)	29/50 (58%)		15/50 (30%) 19/50 (38%)	18/50 (36%)	19/50 (38%)
Overall Incidence	Total	127/250 (50.8%)	Mean 50.8%	SD 5.76%	Total	71/200 (35.5%)	Mean 35.5%	SD 3.79%
#All Organs: Malignant and Benign T	umors							
		50/50 (100%) 50/50 (100%)	50/50 (100%) 50/50 (100%)	50/50 (100%)		47/50 (94%) 48/50 (96%)	46/50 (92%)	48/50 (96%)
Overall Incidence	Total	250/250 (100%)	Mean 100%	SD 0%	Total	189/200 (94.5%)	Mean 94.5%	SD 1.91%
All Organs: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Hemangiosarcoma								
		2/50 (4%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

ontrol Animal Groups

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Report Date:04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female	
All Organs: Hemangiosarcoma or He	emangioma					
•	J	2/50 (4%)	0/50 (0%) 0/50	0 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 3/250 (1.2%)	1/50 (2%) Mean 1.2% S	D 1.79% Total	0/50 (0%) 0/50 (0%) 0/200 (0%) Mean 0%	SD 0%
		` ,	Wican 1.270		, ,	
All Organs: Histiocytic Sarcoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 3/50 (6%)	0 (0%)	1/50 (2%) 2/50 (4%) 0/50 (0%)	1/50 (2%)
verall Incidence	Total	3/250 (1.2%)	` '	D 2.68% Total	2/50 (4%) 0/50 (0%) 4/200 (2%) Mean 2%	SD 1.63%
vo.u moidonos		0,200 (1.2,0)	Wodii 1.270		1,250 (270) Modif 270	05 1.0070
All Organs: Leukemia: Erythrocytic						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	0 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	` '	D 0% Total	0/50 (0%) 1/50 (2%) 1/200 (0.5%) Mean 0.5%	SD 1%
· oran moraonoo		0,200 (0,0)	Modifi 070		1/200 (0.070) Modifi 0.070	
All Organs: Leukemia: Lymphocytic Undifferentiated	, Monocytic, M	Iononuclear, or				
		19/50 (38%)	15/50 (30%) 21/5	50 (42%)	9/50 (18%)	9/50 (18%)
verall Incidence	Total	15/50 (30%) 87/250 (34.8%)	17/50 (34%) Mean 34.8% S	D 5.22% Total	9/50 (18%) 6/50 (12%) 33/200 (16.5%) Mean 16.5%	SD 3%
	Total	` ,			(1 1 1)	3D 3%
NI Organs: Malignant Lymphoma: H or Undifferentiated Cell	listiocytic, Lyn		,			
	71	0/50 (0%)	1/50 (2%) 0/50	0 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	-	0/50 (0%)	0/50 (0%)	D 0 000/	0/50 (0%) 0/50 (0%) 0/200 (0%) Mean 0%	OD 00/
	Total	1/250 (0.4%)	Mean 0.4% S	D 0.89% Total	0/200 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 207

			Male				Female	
All Organs: Mesothelioma: Benign		0/50 (09/)	0/50 (00/)	0/50 (09/)		0/50 /00/		0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs:								
Mesothelioma: Benign, Mal	ilgnant, NOS	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Malignant	•••••							
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Osteoma	•••••				•••••			
Osteoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	2/50 (4%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male	Female
#All Organs: Osteosarcoma or Osteoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2% SD 1.79%	Total 1/200 (0.5%) Mean 0.5% SD 1%
*Adrenal Cortex: Adenoma				
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 2/50 (4%)	2/50 (4%) 1/50 (2%) 1/49 (2%) 0/48 (0%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2% SD 1.79%	Total 4/197 (2.03%) Mean 2.01% SD 1.63%
*Adrenal Cortex: Carcinoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/197 (0%) Mean 0% SD 0%
*Adrenal Medulla: Ganglioneuroma				
· ·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 0/48 (0%) 0/48 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 0/194 (0%) Mean 0% SD 0%
*Adrenal Medulla: Hemangioma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 0/48 (0%) 0/48 (0%) 0/48 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 0/194 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

Page: 208

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 209

			Male				Female					
Adrenal Medulla: Pheochromocytoma Benign												
	3	8/50 (16%) 8/50 (16%)	8/50 (16%) 5/50 (10%)	5/49 (10%)		1/50 (2%) 2/48 (4%)	1/48 (2%)	0/48 (0%)				
verall Incidence	Total	34/249 (13.65%)	Mean 13.64%	SD 3.23%	Total	4/194 (2.06%)	Mean 2.06%	SD 1.7%				
Adrenal Medulla: Pheochromocytoma Co			•••••	•••••								
•	·	0/50 (0%) 2/50 (4%)	0/50 (0%) 1/50 (2%)	0/49 (0%)		0/50 (0%) 0/48 (0%)	1/48 (2%)	0/48 (0%)				
Overall Incidence	Total	3/249 (1.2%)	Mean 1.2%	SD 1.79%	Total	1/194 (0.52%)	Mean 0.52%	SD 1.04%				
Adrenal Medulla: Pheochromocytoma M	alignant											
		3/50 (6%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/49 (2%)		2/50 (4%) 1/48 (2%)	0/48 (0%)	0/48 (0%)				
Overall Incidence	Total	4/249 (1.61%)	Mean 1.61%	SD 2.61%	Total	3/194 (1.55%)	Mean 1.52%	SD 1.92%				
Adrenal Medulla: Pheochromocytoma: B	onian Compley	Malianant NOS										
Fileociii omocytoma. B	enign, complex	11/50 (22%)	8/50 (16%)	6/49 (12%)		3/50 (6%)	0/40 (40/)	0/48 (0%)				
Overall Incidence	Total	10/50 (20%) 41/249 (16.47%)	6/50 (12%) Mean 16.45%	SD 4.5%	Total	3/48 (6%) 8/194 (4.12%)	2/48 (4%) Mean 4.1%	SD 2.89%				
Bone: Chondrosarcoma												
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 210

			Male				Female	
#Bone: Chondrosarcoma or Chondro	oma	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Bone: Chordoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
Bone: Osteosarcoma						•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	2/50 (4%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Bone: Osteosarcoma or Osteoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	2/50 (4%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 211

			Male		Female
*Brain: Astrocytoma Malignant		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%)	6) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 0/200 (0%)	Mean 0% SD 0%
*Brain: Ependymoma Benign		0/50 (0%)	0/50 (0%) 0/49 (0%		0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/249 (0%)	0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/200 (0%)	0/50 (0%) Mean 0% SD 0%
*Brain: Ependymoma Malignant	•••••	0/50 (0%)	0/50 (0%) 1/49 (2%		0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/249 (0.4%)	0/50 (0%) Mean 0.41% SD 0.919	0/50 (0%)	0/50 (0%) Mean 0% SD 0%
*Brain: Glioma Malignant	• • • • • • • • • • • • • • • • • • • •				
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/249 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) Mean 0% SD 0%	%) 0/50 (0%) 0/50 (0%) Total 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
*Brain: Granular Cell Tumor Benig					0/50 (0%)
Overall Incidence	Total	2/50 (4%) 0/50 (0%) 2/249 (0.8%)	0/50 (0%) 0/49 (0%) 0/50 (0%) Mean 0.8% SD 1.79%	0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

: May2009

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 212

			Male				Female	
Brain: Medulloblastoma Mal		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)		0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/40 (070)		0/50 (0%)	0/50 (0%)	0/00 (0/0)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, Mali	anant NOS							
og.oa. 20g.,a	g.iaiii, itoo	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Benig	n							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Maligr								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 213

			Male				Female	
Brain:								
Oligodendroglioma, Gli	ioma, or Astroc	-	0/50 (00/)	0/40 (00/)		0/50 (00/)		0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
					•••••			
Brain: Osteosarcoma								
Osteosarcoma		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)		0/50 (0%)
		0/50 (0%)	0/50 (0%)	2, 10 (0,0)		0/50 (0%)	0/50 (0%)	(0,0)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
					•••••			
Brain: Schwannoma Malignan	.4							
Scriwarinoma Manghan	ıı	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)		0/50 (0%)
		0/50 (0%)	0/50 (0%)	0, 10 (0,0)		0/50 (0%)	0/50 (0%)	(070)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland:								
Adenoma								
		1/50 (2%)	5/50 (10%)	0/50 (0%)		10/50 (20%)		5/50 (10%)
		2/50 (4%)	1/50 (2%)	05 0 050/		8/50 (16%)	11/50 (22%)	
verall Incidence	Total	9/250 (3.6%)	Mean 3.6%	SD 3.85%	Total	34/200 (17%)	Mean 17%	SD 5.29%
Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	2/50 (4%)		0/50 (0%)		4/50 (8%)
		0/50 (0%)	2/50 (4%)	` ,		2/50 (4%)	3/50 (6%)	` '
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 2.19%	Total	9/200 (4.5%)	Mean 4.5%	SD 3.42%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

sion. May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 214

			Male				Female	
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		1/50 (2%) 2/50 (4%)	5/50 (10%) 3/50 (6%)	2/50 (4%)		10/50 (20%) 10/50 (20%)	14/50 (28%)	9/50 (18%)
verall Incidence	Total	13/250 (5.2%)	Mean 5.2%	SD 3.03%	Total	43/200 (21.5%)	Mean 21.5%	SD 4.43%
Clitoral/Preputial Gland: Fibrosarcoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland:								
Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (00()	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Ear: Neural Crest Tumor								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: F344 Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Page: 215

			Male				Female	
#Esophagus: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Esophagus: Lipoma								•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Eye: Amelanotic Melanoma, l								0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Eye: Melanoma Malignant								•••••
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Eye: Schwannoma Malignant	t	0/50 (00/)	4/50 (00())	0/50 (00/)		0/50 (00/)		0/50 (00/)
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 216

			Male				Female	
#Harderian Gland: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/00 (0/0)		0/50 (0%)	0/50 (0%)	0/00 (0/0)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Harderian Gland: Carcinoma or Adenoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Heart: Schwannoma Benign								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	SD 1%
Heart:								
Schwannoma Malignant		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		1/50 (2%)
		0/50 (0%)	1/50 (2%)	(,		0/50 (0%)	0/50 (0%)	(,
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Intestine Large: Colon/Rectur Adenoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Intestine Large: Colon/Rectum: Carcinoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)(0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/250 (0%) 0/200 (0%) **Overall Incidence** Total Mean 0% SD 0% Total Mean 0% SD 0% #Intestine Large: Colon/Rectum: Carcinoma or Adenoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0.4% SD 0.89% Total 0/200 (0%) Mean 0% SD 0% 1/250 (0.4%) #Intestine Large: Colon/Rectum: Hemangioma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%) 0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 1/250 (0.4%) Mean 0.4% SD 0.89% Total 0/200 (0%) Mean 0% #Intestine Small: Duodenum: Carcinoma 1/50 (2%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)**Overall Incidence** 1/250 (0.4%) SD 0.89% SD 0% Total Mean 0.4% Total 0/200 (0%) Mean 0% #Intestine Small: Duodenum: Leiomyoma (0%)0/50 (0%)0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%)Mean 0% SD 0% Total 0/200 (0%)Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 218

			Male				Female	
fintestine Small: Jejunum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Intestine Small: Jejunum: Granular Cell Tumor Ma								
	J	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
fIntestine Small: Jejunum: Leiomyoma								
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Leiomyosarcoma								
2010my Cour Coma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
		, ,				,		
Intestine Small: Site Unspe Carcinoma	ecified:							
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

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Species: RATS

Route: ORAL

Length of Study: CHRONIC

Vehicle: FEED

			Male		Female	
Intestine Small: Site Unsp Carcinoma or Adenom						
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	` '	0.89% Total	0/200 (0%)	SD 0%
ntestine Small: Site Unsp Granular Cell Tumor M						
	· ·	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/250 (0%)	` '	0% Total	0/200 (0%) Mean 0%	SD 0%
Intestine Small: Site Uns Leiomyoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD	0% Total	0/200 (0%) Mean 0%	SD 0%
ntestine Small: Site Unsp						
Leiomyosarcoma		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0% SD	0% Total	0/50 (0%) 0/50 (0%) 0/200 (0%) Mean 0%	SD 0%
Islets, Pancreatic: Adenoma						
		1/50 (2%) 3/50 (6%)	1/49 (2%) 7/50 3/50 (6%)	(14%)	2/49 (4%) 0/49 (0%) 0/48 (0%)	0/49 (0%)
Overall Incidence	Total	15/249 (6.02%)	` ,	4.89% Total	2/195 (1.03%) Mean 1.02%	SD 2.04%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: RATS

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

			Male				Female	
Islets, Pancreatic: Carcinoma								
		1/50 (2%)	1/49 (2%)	0/50 (0%)		0/49 (0%)	0/40 (00/)	0/49 (0%)
Overall Incidence	Total	0/50 (0%) 3/249 (1.2%)	1/50 (2%) Mean 1.21%	SD 1.1%	Total	0/49 (0%) 0/195 (0%)	0/48 (0%) Mean 0%	SD 0%
	1 Olai	,	Wearr 1.21/6			,		
slets, Pancreatic: Carcinoma or Adenoma	ı							
		2/50 (4%)	2/49 (4%)	7/50 (14%)		2/49 (4%)	0/40 (00/)	0/49 (0%)
Verall Incidence	Total	3/50 (6%)	4/50 (8%)	CD 4.420/	Total	0/49 (0%)	0/48 (0%)	CD 2.040/
Overall Incidence	Total	18/249 (7.23%)	Mean 7.22%	SD 4.13%	Total	2/195 (1.03%)	Mean 1.02%	SD 2.04%
Kidney: Pelvis and Transiti Carcinoma		m:	•••••			•••••		
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/47 (0%)		0/49 (0%)
		0/48 (0%)	0/50 (0%)			0/48 (0%)	0/48 (0%)	
verall Incidence	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/192 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transiti Carcinoma or Adenoma	ional Epitheliu							
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/47 (0%)		0/49 (0%)
		0/48 (0%)	0/50 (0%)			0/48 (0%)	0/48 (0%)	
verall Incidence	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/192 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Transiti Papilloma								
		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 1/48 (2%)	0/48 (0%)	0/49 (0%)
		U/40 (U70)	0/30 (0%)			1/40 (270)	0/48 (0%)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Kidney: Renal Tubule: Adenoma 0/50 (0%)0/50 (0%)(0%)0/47 (0%)0/49 (0%)(0%)(0%)(0%)0/48 0/50 0/48 0/48 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% Total 0/192 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma 0/50 (0%)0/50 (0%)0/47 (0%)(0%)0/48 (0%)(0%)0/48 (0%)0/48 **Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% Total 0/192 (0%) Mean 0% SD 0% *Kidney: Renal Tubule: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)(0%)0/47 (0%)0/49 (0%)(0%)0/48 (0%)0/50 (0%)0/48 **Overall Incidence** SD 0% SD 0% Total 0/248 (0%) Mean 0% Total 0/192 (0%) Mean 0% *Kidney: Renal Tubule: Hemangiosarcoma (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/48 (0%)0/50 (0%)0/48 (0%)(0%)**Overall Incidence** Mean 0% SD 0% 0/192 (0%) SD 0% Total 0/248 (0%) Total Mean 0% *Kidney: Renal Tubule: Lipoma (0%)0/50 (0%)0/50 0/50 (0%)0/49 (0%)0/48 (0%)0/50 (0%)0/48 (0%)0/48 (0%)**Overall Incidence** Total 0/248 (0%)Mean 0% SD 0% Total 0/192 (0%) Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 222

			Male		Female
Kidney: Renal Tubule: Mesenchymal Tumor Be	nign				
·		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	%) 0/47 (0%) 0/48 (0%)	0/49 (0%) 0/48 (0%)
overall Incidence	Total	0/248 (0%)	Mean 0% SD 0%	Total 0/192 (0%)	Mean 0% SD 0%
Kidney: Renal Tubule: Nephroblastoma					
		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	%) 0/47 (0%) 0/48 (0%)	0/49 (0%) 0/48 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0% SD 0%	Total 0/192 (0%)	Mean 0% SD 0%
Kidney: Renal Tubule: Sarcoma					
		0/50 (0%) 1/48 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	%) 0/47 (0%) 0/48 (0%)	1/49 (2%) 0/48 (0%)
overall Incidence	Total	1/248 (0.4%)	Mean 0.42% SD 0.93	` ,	0/48 (0%) Mean 0.51% SD 1.02%
_iver:					
Cholangioma		1/50 (2%)	0/50 (0%) 0/50 (0%)		0/50 (0%)
verall Incidence	Total	0/50 (0%) 2/250 (0.8%)	1/50 (2%) Mean 0.8% SD 1.1%	0/50 (0%) 5 Total 0/200 (0%)	0/50 (0%) Mean 0% SD 0%
Liver: Hemangiosarcoma		0/50 (0%)	0/50 (0%) 0/50 (09	0/50 (00/)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/200 (0%)	Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			Male				Female	
*Liver: Hepatocellular Adenoma		1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%)		0/50 (0%)
		0/50 (0%)	3/50 (6%)	(11,		0/50 (0%)	2/50 (4%)	(111)
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.45%	Total	4/200 (2%)	Mean 2%	SD 2.31%
*Liver: Hepatocellular Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incluence	TOtal	0/230 (0 /8)	IVICALI 076	30 0%	I Olai	0/200 (0 /8)	iviean 076	3D 0%
*Liver: Hepatocellular Carcinoma o	or Hepatob	lastoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Liver:	• • • • • • • • • • • • • • • • • • • •							
Hepatocellular Carcinoma o	or Hepatoco		0/50 (00/)	4/50 (00/)		0/50 /40/)		0/50 (00/)
		1/50 (2%) 0/50 (0%)	0/50 (0%) 3/50 (6%)	1/50 (2%)		2/50 (4%) 0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.45%	Total	4/200 (2%)	Mean 2%	SD 2.31%
*Liver: Hepatocellular Carcinoma, Hepatoblastoma	Hepatocell	ular Adenoma, or						
		1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%)	0/50 (40/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	3/50 (6%)	SD 2.4E9/	Total	0/50 (0%)	2/50 (4%)	CD 2.210/
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.45%	Total	4/200 (2%)	Mean 2%	SD 2.31%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female	
*Lung: Alveolar/Bronchiolar Ade	enoma	0/50 (0%)	1/50 (2%)	0/50 (0%)	1/50 (2%)	1/50	(2%)
Overall Incidence	Total	0/50 (0%) 2/250 (0.8%)	1/50 (2%) Mean 0.8%	SD 1.1%	0/50 (0%) Total 2/200 (1%)	0/50 (0%)	1.15%
*Lung: Alveolar/Bronchiolar Car	cinoma						
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/250 (0.4%)	0/50 (0%) 0/50 (0%) Mean 0.4%	1/50 (2%) SD 0.89%	0/50 (0%) 0/50 (0%) Total 1/200 (0.5%)	0/50 1/50 (2%) Mean 0.5% SD	(0%) 1%
*Lung: Alveolar/Bronchiolar Car Adenoma	cinoma or Alv	veolar/Bronchiolar					
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 3/250 (1.2%)	1/50 (2%) 1/50 (2%) Mean 1.2%	1/50 (2%) SD 1.1%	1/50 (2%) 0/50 (0%) Total 3/200 (1.5%)	1/50 1/50 (2%) Mean 1.5% SD	(2%) 1%
*Lung: Fibrosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50	(0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	0/50 (0%) Total 0/200 (0%)	0/50 (0%) Mean 0% SD	0%
*Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50	(0%)
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	0/50 (0/6) 0/50 (0%) Total 0/200 (0%)	0/50 (0%) Mean 0% SD	,

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Lung: Sarcoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)(0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 (0%)0/200 (0%) **Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total Mean 0% SD 0% *Lung: Squamous Cell Carcinoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0.4% SD 0.89% Total 0/200 (0%) Mean 0% SD 0% 1/250 (0.4%) #Lymph Node: Hemangiosarcoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/250 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% #Mammary Gland: Adenolipoma (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)**Overall Incidence** 0/250 (0%) SD 0% SD 0% Total Mean 0% Total 0/200 (0%) Mean 0% #Mammary Gland: Adenoma (2%)0/50 (0%)1/50 0/50 (0%)2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/250 (0.4%)Mean 0.4% SD 0.89% Total 3/200 (1.5%) Mean 1.5% SD 1.91%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 226

				Ma	ale						Fema	ale		
#Mammary Gland: Carcinoma														
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/50 2/50	(0%) (4%)	4/50	(8%)	4/50	(8%)
verall Incidence	Total	0/250	` ,	Mean			0%	Total	10/200	` ,	Mear			3.83%
Mammary Gland: Carcinoma or Adenoma							•••••		•••••			•••••		
		0/50 0/50	(0%) (0%)	1/50 0/50	(2%) (0%)	0/50	(0%)		1/50 2/50	(2%) (4%)	4/50	(8%)	6/50	(12%)
Overall Incidence	Total	1/250	(0.4%)	Mean	0.4%	SD	0.89%	Total	13/200	(6.5%)	Mear	n 6.5%	SD	4.43%
Mammary Gland: Fibroadenoma				•••••			•••••		•••••			•••••	•••••	
		2/50 3/50	(4%) (6%)	0/50 0/50	(0%) (0%)	1/50	(2%)		29/50 24/50	(58%) (48%)	28/50	(56%)	30/50	(60%)
Overall Incidence	Total	6/250	(2.4%)	Mean	2.4%		2.61%	Total	111/200	(55.5%)	Mear	n 55.5%		5.26%
Mammary Gland: Fibroma				•••••	•••••		•••••		•••••			• • • • • • • • • • • • • • • • • • • •	•••••	
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
overall Incidence	Total	0/250	` '	Mean	, ,	SD	0%	Total	0/200 (` '	Mear	` '	SD	0%
Mammary Gland: Fibroma, Fibroadenoma or			•••••							•••••		•••••		
· ····· · · · · · · · · · · · · · · ·		2/50 3/50	(4%) (6%)	1/50 0/50	(2%) (0%)	1/50	(2%)		30/50 24/50	(60%) (48%)	28/50	(56%)	30/50	(60%)
Overall Incidence	Total	7/250	` ,		2.8%	SD	2.28%	Total	112/200	` ,		(56%) n 56%	SD	5.66%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female	
#Mammary Gland: Fibroma, Fibroadenoma,	Carcinoma, o	r Adenoma				
		2/50 (4%) 3/50 (6%)	1/50 (2%) 1/50 0/50 (0%)) (2%)	30/50 (60%) 25/50 (50%) 28/50 (56%)	31/50 (62%)
Overall Incidence	Total	7/250 (2.8%)		D 2.28% Total	114/200 (57%) Mean 57%	SD 5.29%
#Mesentery: Fibrosarcoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	0 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	()	D 0% Total	1/200 (0.5%) Mean 0.5%	SD 1%
#Mesentery: Hemangiosarcoma						
•		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50	0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	0/50 (0%) Mean 0.4% S	D 0.89% Total	0/50 (0%) 0/50 (0%) 0/200 (0%) Mean 0%	SD 0%
#Mesentery: Lipoma						
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 0/50 (0%)) (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	` '	D 0.89% Total	0/50 (0%) 0/50 (0%) 0/200 (0%) Mean 0%	SD 0%
#Mesentery: Rhabdomyosarcoma						
		0/50 (0%)	0/50 (0%) 0/50	0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0% S	D 0% Total	0/50 (0%) 0/50 (0%) 0/200 (0%) Mean 0%	SD 0%
		` '				

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 228

			Male				Female	
Nose:								
Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/00 (0/0)		0/49 (0%)	0/50 (0%)	0/00 (0/0)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Nose:		•••••	•••••			•••••		•••••
Chondroma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%
verali incidence	i Olai	0/249 (0%)	Mean 0%	3D 0%	I Olai	0/199 (0%)	Mean 0%	3D 0%
Nose: Squamous Cell Carcino	ma							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)
		0/49 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa,		vnx, Tooth, Gingiva):						
Papilloma Squamous or	r Papilloma		2 (22 (22 (22 (22 (22 (22 (22 (22 (22 (. (=0 (00)		2/22 (22/)		. (=0 (00)
		1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total		1/50 (2%) Mean 1.2%	SD 1.1%	Total	(/	0/50 (0%) Mean 0.5%	SD 1%
		3/250 (1.2%)				1/200 (0.5%)		
Oral Cavity (Oral Mucosa, Squamous Cell Carcino	Tongue, Phary							
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/30 (0%)	0/30 (0%)			0/30 (0%)	0/30 (0%)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: FEED

			Male	Female
#Oral Cavity (Oral Mucosa, Tor Squamous Cell Carcinoma				
Papilloma		1/50 (2%) 0/50 (0%)	0/50 (0%) 2/50 (4%) 1/50 (2%)	0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6% SD 1.67%	Total 1/200 (0.5%) Mean 0.5% SD 1%
#Oral Mucosa: Squamous Cell Carcinoma	· · · · · · · · · · · · · · · · · · ·			
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SD 0.89%	Total 0/200 (0%) Mean 0% SD 0%
#Oral Mucosa: Squamous Cell Papilloma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%
*Ovary: Cystadenoma				
Cystadenoma				0/50 (0%) 0/50 (0%)
Overall Incidence				0/50 (0%) 0/50 (0%) Total 0/200 (0%) Mean 0% SD 0%
*Ovary: Granulosa Cell Tumor Ben	ian			
Granulosa Cell Tullior Bell	igii			0/50 (0%)
Overall Incidence				Total 0/200 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Page: 230

Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

	Male		Female	
*Ovary: Granulosa Cell Tumor Malignant				
C. a. a. c.		0/50 (0%)	0/50 (40/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 2/200 (1%)	2/50 (4%) Mean 1%	SD 2%
*Ovary:				
Granulosa Cell Tumor: Benign, Malignant, NOS		0/50 (0%)		0/50 (0%)
Overall leaders	Tatal	0/50 (0%)	2/50 (4%)	CD 201/
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%
*Ovary:				•••••
Granulosa-Theca Tumor Benign		1/50 (2%)		0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0.5%	SD 1%
Overall incidence	rotar	1/200 (0.5%)	Mean 0.5%	SD 1%
*Ovary:				
Granulosa-Theca Tumor Malignant		0/50 (0%)		0/50 (0%)
	-	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%
*Ovary:				
Tubulostromal Adenoma		0/50 (0%)		0/50 (0%)
		0/50 (0%)	0/50 (0%)	(111)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 231 Report Date: 04/29/2009

Species: RATS Strain: F344 Route: ORAL Vehicle: FEED

			Male	Female
*Pancreas: Adenoma				
		0/49 (0%) 1/50 (2%)	0/49 (0%) 0/50 (0%) 2/50 (4%)	0/49 (0%)
Overall Incidence	Total	3/248 (1.21%)	Mean 1.2% SD 1.79%	Total 0/195 (0%) Mean 0% SD 0%
*Pancreas: Carcinoma				
		0/49 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0% SD 0%	Total 0/195 (0%) Mean 0% SD 0%
*Pancreas: Carcinoma or Adenoma				
		0/49 (0%) 1/50 (2%)	0/49 (0%) 0/50 (0%) 2/50 (4%)	0/49 (0%)
Overall Incidence	Total	3/248 (1.21%)	Mean 1.2% SD 1.79%	Total 0/195 (0%) Mean 0% SD 0%
*Pancreas: Mixed Tumor Benign		•••••		
_		0/49 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0% SD 0%	Total 0/195 (0%) Mean 0% SD 0%
*Pancreas: Mixed Tumor Malignant				
		0/49 (0%) 0/50 (0%)	0/49 (0%) 1/50 (2%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/248 (0.4%)	Mean 0.4% SD 0.89%	Total 0/195 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED ps **Report Date**:04/29/2009

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			Male				Female	
Parathyroid Gland:								
Adenoma		1/45 (2%)	1/46 (2%)	0/49 (0%)		0/48 (0%)		0/49 (0%)
		1/48 (2%)	0/50 (0%)	(0,0)		0/50 (0%)	0/49 (0%)	(57.5)
verall Incidence	Total	3/238 (1.26%)	Mean 1.3%	SD 1.18%	Total	0/196 (0%)	Mean 0%	SD 0%
Peripheral Nerve: Schwannoma Malignant						•••••		
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (09/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
/verall illelidelide	I Olai	0/230 (0/8)	Wearr 070	3D 070	I Olai	0/200 (0/0)	Weatt 070	30 0%
#Peripheral Nerve: Schwannoma: Benign, N	lalignant, NOS	3						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Pituitary Gland: Pars Distali Adenoma		ied Site:						
		10/50 (20%)	20/50 (40%)	8/50 (16%)		24/49 (49%)	00/50 (400/)	25/50 (50%)
Overall Incidence	Tatal	16/49 (33%)	13/50 (26%)	CD 0.040/	Tatal	29/48 (60%)	20/50 (40%) Mean 49.85%	CD 0.000/
	Total	67/249 (26.91%)	Mean 26.93%	SD 9.64%	Total	98/197 (49.75%)		SD 8.36%
Pituitary Gland: Pars Distal						•••••		•••••
Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/49 (2%)	4/50 (00/)	0/50 (0%)
Carcinoma		0/49 (0%)	0/50 (0%)			0/48 (0%)	1/50 (2%)	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

. Way2000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 233

			Male		Female	
Pituitary Gland: Pars Distalis Carcinoma or Adenoma	or Unspecif	ied Site:				
Carollia of Adelionia		10/50 (20%) 16/49 (33%)	20/50 (40%) 8/50 13/50 (26%)	(16%)	25/49 (51%) 29/48 (60%) 21/50 (42%)	25/50 (50%)
overall Incidence	Total	67/249 (26.91%)	Mean 26.93% SD 9	9.64% Total	100/197 (50.76%) Mean 50.86%	SD 7.54%
Pituitary Gland: Pars Distalis Ganglioneuroma						•••••
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)	0/49 (0%) 0/48 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD (0% Total	0/197 (0%) Mean 0%	SD 0%
Pituitary Gland: Pars Interme Adenoma						
		0/50 (0%) 0/49 (0%)	1/50 (2%) 0/50 0/50 (0%)	(0%)	0/49 (0%) 0/48 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	` ,	0.89% Total	0/197 (0%)	SD 0%
Pituitary Gland: Pars Interme Carcinoma						
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0% SD (0% Total	0/48 (0%) 0/50 (0%) 0/197 (0%) Mean 0%	SD 0%
Pituitary Gland: Pars Interme Carcinoma or Adenoma						
		0/50 (0%) 0/49 (0%)	1/50 (2%) 0/50 0/50 (0%)	(0%)	0/49 (0%) 0/48 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	` ,	0.89% Total	0/48 (0%) 0/30 (0%) 0/197 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 234

			Male	Female
*Prostate: Adenoma		0.70		
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SD 0.89%	
*Prostate: Carcinoma or Adenoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)	
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SD 0.89%	
*Salivary Glands: Sarcoma				
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/48 (0%)	0/50 (0%)
Overall Incidence	Total	0/247 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%
#Seminal Vesicle: Adenoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	
#Skeletal Muscle: Fibrous Histiocytoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 235

			Male				Female	
#Skeletal Muscle: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma	•••••							
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle:								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle:						•••••		
Rhabdomyosarcoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	- 1 1 1	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
		,				,		30 0%
Skeletal Muscle: Rhabdomyosarcoma or	Rhabdomyom		0/50 (09/)	1/50 (29/)		0/50 (09/)		0/50 (09/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

te: ORAL

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: ORAL Vehicle: FEED

				M	ale					Female	•		
#Skeletal Muscle: Sarcoma													
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50 (0%)		0/50 0/50	(0%) (0%)	0/50 (0%)	0/50	(0%)
Overall Incidence	Total		(0%)	Mean		SD 0%	Total	0/200 (,	Mean		SD	
Skin: Basal Cell Adenoma													
		1/50 1/50	(2%) (2%)	0/50 0/50	(0%) (0%)	0/50 (0%)		0/50 0/50	(0%) (0%)	0/50 (0%)	0/50	(0%)
Overall Incidence	Total	2/250	` ,		0.8%	SD 1.1%	Total	0/200 (` ,	Mean	,	SD	0%
Overall Incidence	Total	1/50 1/50 2/250	(2%) (2%) (0.8%)	0/50 0/50 Mean	(0%) (0%) 0.8%	0/50 (0%) SD 1.1%	Total	0/50 0/50 0/200 ((0%) (0%) 0%)	0/50 (Mean	0%) 0%	0/50 SD	(0%) 0%
	iotai	2/200	(/					0,200 (,	ivican	0 70		
Skin:								0,200 (,				
		Г umor Be n 1/50	ign, or (2%)	0/50	(0%)	0/50 (0%)		0/50	(0%)			1/50	(2%)
Skin: Basal Cell Adenoma, Bas Trichoepithelioma		Tumor Ben	ign, or (2%) (2%)	0/50 0/50	(0%) (0%) 0.8%	0/50 (0%) SD 1.1%	Total	······································	(0%) (2%)		0%)	1/50	(2%) 1.15%
Skin: Basal Cell Adenoma, Bas Trichoepithelioma Overall Incidence	sosquamous ⁻ Total	Tumor Ben 1/50 1/50 2/250	ign, or (2%) (2%) (0.8%)	0/50 0/50 Mean	(0%) 0.8%	SD 1.1%		0/50 1/50 2/200 ((0%) (2%) 1%)	0/50 (Mean	0%) 1%	1/50 SD	1.15%
#Skin: Basal Cell Adenoma, Bas Trichoepithelioma Overall Incidence #Skin:	sosquamous ⁻ Total	Tumor Ben 1/50 1/50 2/250	ign, or (2%) (2%) (0.8%)	0/50 0/50 Mean	(0%) 0.8%	SD 1.1%		0/50 1/50 2/200 ((0%) (2%) 1%)	0/50 (Mean	0%) 1%	1/50 SD	1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			ľ	/lale				Female	
Skin: Basal Cell Carcinoma NOS)	or Basosquamo	us Tumor (mal	lignant or						
1100)		0/50 (0%) 0/50	(0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)
		0/50	0%) 1/50	(2%)	, ,		0/50 (0%)	0/50 (0%)	, ,
Overall Incidence	Total	1/250 (0.4	•	ın 0.4%	SD 0.89%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma, Tumor (benign, maligr	, Basal Cell Ader	noma, Basosqu Trichoepithelio	uamous oma						
			2%) 0/50 2%) 1/50	(0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/250 (1.2	•	(2%) ın 1.2%	SD 1.1%	Total	2/200 (1%)	0/50 (0%) Mean 1%	SD 1.15%
, veran incluence	i otal	3/230 (1.2	/u) IVIE	III 1.Z/0	JD 1.170	i otal	21200 (170)	IVICALL 170	JD 1.13/0
#Skin: Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar	oma, Adenoma,	Papilloma, Sq							
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar	oma, Adenoma, nthoma, Trichoe	Papilloma, Sq pithelioma 4/50 (3/50 (8%) 1/50 6%) 6/50	(2%) (12%)	2/50 (4%)		0/50 (0%) 2/50 (4%)	1/50 (2%)	1/50 (2%)
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar	oma, Adenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 4/50 (3/50 (16/250 (6.40)	8%) 1/50 6%) 6/50 4%) Mea	(12%) In 6.4%	SD 3.85%	Total	2/50 (4%) 4/200 (2%)	Mean 2%	SD 1.63%
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar Overall Incidence	oma, Adenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 4/50 (3/50 (16/250 (6.40)	8%) 1/50 6%) 6/50 4%) Mea	(12%) In 6.4%	SD 3.85%		2/50 (4%) 4/200 (2%)	Mean 2%	SD 1.63%
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar Overall Incidence	oma, Adenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 4/50 (6 3/50 (6 16/250 (6.	8%) 1/50 6%) 6/50 4%) Mea	(12%) In 6.4% (2%)	SD 3.85%		2/50 (4%) 4/200 (2%) 0/50 (0%)	Mean 2%	SD 1.63%
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar Overall Incidence #Skin: Fibroma	oma, Adenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 4/50 (i 3/50 (i 16/250 (6	8%) 1/50 6%) 6/50 4%) Mea 	(12%) un 6.4% (2%) (6%)	SD 3.85% 5/50 (10%)		2/50 (4%) 4/200 (2%) 0/50 (0%) 1/50 (2%)	Mean 2%	SD 1.63%
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar Overall Incidence #Skin: Fibroma Overall Incidence	oma, Adenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 4/50 (6.3/50 (6.16/25	8%) 1/50 6%) 6/50 4%) Mea 	(12%) an 6.4% (2%) (6%) an 8.4%	SD 3.85% 5/50 (10%) SD 5.18%	Total	2/50 (4%) 4/200 (2%) 0/50 (0%) 1/50 (2%) 3/200 (1.5%)	Mean 2% 1/50 (2%) Mean 1.5%	SD 1.63% 1/50 (2%) SD 1%
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar Overall Incidence #Skin: Fibroma	Total Total Total	Papilloma, Sq pithelioma 4/50 (3/50 (6.16/250	8%) 1/50 6%) 6/50 4%) Mea 8%) 1/50 16%) 3/50 4%) Mea	(12%) an 6.4% (2%) (6%) an 8.4%	SD 3.85% 5/50 (10%) SD 5.18%	Total	2/50 (4%) 4/200 (2%) 0/50 (0%) 1/50 (2%) 3/200 (1.5%)	Mean 2%	SD 1.63% 1/50 (2%) SD 1%
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar Overall Incidence #Skin: Fibroma Overall Incidence #Skin: Fibroma Fibroma	Total Total Total	Papilloma, Sq pithelioma 4/50 (i 3/50 (i 16/250 (6	8%) 1/50 6%) 6/50 4%) Mea 	(12%) in 6.4%	SD 3.85% 5/50 (10%) SD 5.18%	Total	2/50 (4%) 4/200 (2%) 0/50 (0%) 1/50 (2%) 3/200 (1.5%)	Mean 2% 1/50 (2%) Mean 1.5%	SD 1.63% 1/50 (2%) SD 1%
Basal or Sq. Cell Carc or B), Basal Cell Aden Papilloma, Keratoacar Overall Incidence #Skin: Fibroma Overall Incidence #Skin: Fibroma Fibroma	Total Total Total	Papilloma, Sq pithelioma 4/50 (i 3/50 (i 16/250 (6	8%) 1/50 6%) 6/50 4%) Mea 8%) 1/50 16%) 3/50 4%) Mea rcoma, or 8%) 4/50 16%) 4/50	(12%) an 6.4% (2%) (6%) an 8.4%	SD 3.85% 5/50 (10%) SD 5.18%	Total	2/50 (4%) 4/200 (2%) 0/50 (0%) 1/50 (2%) 3/200 (1.5%)	Mean 2% 1/50 (2%) Mean 1.5%	SD 1.63% 1/50 (2%) SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Fibrosarcoma								
Fibrosarcoma		0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Fibrosarcoma, Sarcoma, M	/lyxosarcom	a, or Fibrous			•••••			
nistiocytoma		0/50 (0%) 0/50 (0%)	3/50 (6%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	2/50 (4%)
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 2.61%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
#Skin: Fibrous Histiocytoma					•••••	•		
ribious histiocytolila		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma			(00)					(201)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Keratoacanthoma 3/50 1/50 (4%)0/50 (0%)(0%)(2%)1/50 4/50 (8%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 11/250 (4.4%) Mean 4.4% SD 2.61% Total 0/200 (0%) Mean 0% SD 0% #Skin: Lipoma 0/50 (0%)1/50 0/50 (0%)(0%)0/50 (0%)(2%)0/50 (0%)0/50 **Overall Incidence** Total 3/250 (1.2%) SD 1.1% Total 0/200 (0%) Mean 0% SD 0% Mean 1.2% #Skin: Liposarcoma 0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/250 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% #Skin: **Neural Crest Tumor** 1/50 (2%)0/50 (0%)(0%)(2%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)**Overall Incidence** 1/250 (0.4%) SD 0.89% SD 1% Total Mean 0.4% Total 1/200 (0.5%) Mean 0.5% #Skin: **Neural Crest Tumor, Malignant** 0/50 (0%)(0%)(0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/250 (0.4%)Mean 0.4% SD 0.89% Total 0/200 (0%)Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			Male				Female	
#Skin: Neurofibroma or Schw	vannoma benign	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)
		0/50 (0%)	0/50 (0%)	(3.3.7)		0/50 (0%)	0/50 (0%)	(3.1.7)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin:			•••••					
Neurofibrosarcoma or	Schwannoma (r	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, N malignant or NOS) Overall Incidence	leurofibroma, or Total	Schwannoma (benign, 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Sarcoma		0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	2/200 (1%)	Mean 1%	SD 2%
#Skin: Schwannoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 241 Report Date:04/29/2009

			Male				Female	
#Skin: Schwannoma Malignant								
· ·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Carcinon	ma					•••••		•••••
		0/50 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Squamous Cell Carcinor Basosquamous Tumor (
Overall Incidence	Total	0/50 (0%) 1/50 (2%) 3/250 (1.2%)	0/50 (0%) 2/50 (4%) Mean 1.2%	0/50 (0%) SD 1.79%	Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	1/50 (2%) Mean 0.5%	0/50 (0%) SD 1%
		1/50 (2%) 3/250 (1.2%) 	2/50 (4%) Mean 1.2% 	,	Total	0/50 (0%) 1/200 (0.5%) 	Mean 0.5%	,
Skin: Squamous Cell Papillom		1/50 (2%) 3/250 (1.2%)	2/50 (4%) Mean 1.2%	SD 1.79%	Total Total	0/50 (0%) 1/200 (0.5%)	` '	SD 1%
Skin: Squamous Cell Papillom Overall Incidence Skin:	n a Total	1/50 (2%) 3/250 (1.2%) 0/50 (0%) 0/50 (0%) 1/250 (0.4%)	2/50 (4%) Mean 1.2% 0/50 (0%) 1/50 (2%)	SD 1.79%		0/50 (0%) 1/200 (0.5%) 0/50 (0%) 1/50 (2%)	Mean 0.5%	SD 1% 0/50 (0%)
Overall Incidence #Skin: Squamous Cell Papillom Overall Incidence #Skin: Squamous Cell Papillom	n a Total	1/50 (2%) 3/250 (1.2%) 0/50 (0%) 0/50 (0%) 1/250 (0.4%)	2/50 (4%) Mean 1.2% 0/50 (0%) 1/50 (2%)	SD 1.79%		0/50 (0%) 1/200 (0.5%) 0/50 (0%) 1/50 (2%)	Mean 0.5%	SD 1% 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 242

Report Date:04/29/2009

Route: ORAL Vehicle: FEED

			Male				Female	
#Skin: Squamous Cell Papillor Carcinoma or Keratoac		Squamous Cell						
		3/50 (6%) 2/50 (4%)	1/50 (2%) 6/50 (12%)	2/50 (4%)		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	14/250 (5.6%)	Mean 5.6%	SD 3.85%	Total 2	2/200 (1%)	Mean 1%	SD 1.15%
#Skin: Squamous Cell Papillor	ma, Papilloma,	or Keratoacanthoma						
·	•	3/50 (6%) 1/50 (2%)	1/50 (2%) 5/50 (10%)	2/50 (4%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	12/250 (4.8%)	Mean 4.8%	SD 3.35%	Total 1	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Trichoepithelioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total 2	2/200 (1%)	Mean 1%	SD 1.15%
#Skin: Sebaceous Gland: Adenoma			0/50 (00/)	0/50 (00/)		0/50 (00/)		0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total (0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma		- /	- 1 ()					- ()
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total (0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS

Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 243

			Male				Female	
Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Spinal Cord: Astrocytoma Benign	•••••				•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spinal Cord: Astrocytoma Malignant			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spinal Cord: Glioma Malignant								
3		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (00()	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Spleen: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/40 (0%)	0/49 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/49 (0%) Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female
*Spleen: Fibrous Histiocytoma				
•		0/50 (0%) 0/50 (0%)	0/49 (0%) 1/49 (2%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%)
Overall Incidence	Total	1/248 (0.4%)	Mean 0.41% SD 0.91%	Total 0/198 (0%) Mean 0% SD 0%
Spleen: Hemangioma				
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0% SD 0%	Total 0/198 (0%) Mean 0% SD 0%
Spleen: Hemangiosarcoma				
3		1/50 (2%) 0/50 (0%)	0/49 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%)
Overall Incidence	Total	1/248 (0.4%)	Mean 0.4% SD 0.89%	Total 0/198 (0%) Mean 0% SD 0%
Spleen: Leiomyosarcoma				
•		1/50 (2%) 0/50 (0%)	0/49 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%)
verall Incidence	Total	1/248 (0.4%)	Mean 0.4% SD 0.89%	Total 0/198 (0%) Mean 0% SD 0%
Spleen: Sarcoma				
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0% SD 0%	Total 0/198 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 245
Report Date: 04/29/2009

Species: RATS Strain: F344 Route: ORAL Vehicle: FEED

			Male				Female	
Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma				•••••			•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma	or Papillon	na Squamous			• • • • • • • • • • • • • • • • • • • •			
·	-	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Stomach, Forestomach: Squamous Cell Papilloma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Stomach, Glandular: Lipoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 246

			Male				Female	
#Stomach, Glandular: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Testes: Adenoma								•••••
		46/50 (92%) 46/50 (92%)	49/50 (98%) 46/50 (92%)	42/50 (84%)				
Overall Incidence	Total	229/250 (91.6%)	Mean 91.6%	SD 4.98%				
Гhymus: Sarcoma								•••••
		0/48 (0%) 0/48 (0%)	0/47 (0%) 0/41 (0%)	0/48 (0%)		0/46 (0%) 0/47 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/232 (0%)	Mean 0%	SD 0%	Total	0/192 (0%)	Mean 0%	SD 0%
Thymus: Thymoma Benign								
,		0/48 (0%) 0/48 (0%)	0/47 (0%) 0/41 (0%)	1/48 (2%)		0/46 (0%) 0/47 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/232 (0.43%)	Mean 0.42%	SD 0.93%	Total	0/192 (0%)	Mean 0%	SD 0%
Fhymus: Thymoma Malignant								
,		0/48 (0%) 0/48 (0%)	0/47 (0%) 0/41 (0%)	0/48 (0%)		0/46 (0%) 0/47 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/232 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Thymus: Thymoma NOS								
		0/48 (0%) 0/48 (0%)	0/47 (0%) 0/41 (0%)	0/48 (0%)		0/46 (0%) 0/47 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/232 (0%)	Mean 0%	SD 0%	Total	0/192 (0%)	Mean 0%	SD 0%
Гhymus: Thymoma: Benign, Maligna								
		0/48 (0%) 0/48 (0%)	0/47 (0%) 0/41 (0%)	1/48 (2%)		0/46 (0%) 0/47 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	1/232 (0.43%)	Mean 0.42%	SD 0.93%	Total	0/192 (0%)	Mean 0%	SD 0%
Гhyroid Gland: C-Cell: Adenoma								
		5/50 (10%) 11/47 (23%)	6/50 (12%) 5/48 (10%)	7/50 (14%)		3/49 (6%) 10/47 (21%)	2/47 (4%)	4/50 (8%)
verall Incidence	Total	34/245 (13.88%)	Mean 13.96%	SD 5.51%	Total	19/193 (9.84%)	Mean 9.91%	SD 7.73%
hyroid Gland: C-Cell: Carcinoma								
		4/50 (8%) 0/47 (0%)	1/50 (2%) 1/48 (2%)	1/50 (2%)		1/49 (2%) 1/47 (2%)	0/47 (0%)	1/50 (2%)
verall Incidence	Total	7/245 (2.86%)	Mean 2.82%	SD 3.03%	Total	3/193 (1.55%)	Mean 1.54%	SD 1.03%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		9/50 (18%) 11/47 (23%)	7/50 (14%) 6/48 (13%)	8/50 (16%)		4/49 (8%) 11/47 (23%)	2/47 (4%)	5/50 (10%)
Overall Incidence	Total	41/245 (16.73%)	Mean 16.78%	SD 4.24%	Total	22/193 (11.4%)	Mean 11.46%	SD 8.32%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female
*Thyroid Gland: Follicular Cell: Adenoma				
		2/50 (4%) 0/47 (0%)	0/50 (0%) 0/50 (0%) 0/48 (0%)	0/49 (0%)
Overall Incidence	Total	2/245 (0.82%)	Mean 0.8% SD 1.79%	Total 2/193 (1.04%) Mean 1.06% SD 2.13%
*Thyroid Gland: Follicular Cell: Carcinoma				
		0/50 (0%) 0/47 (0%)	0/50 (0%) 0/50 (0%) 0/48 (0%)	0/49 (0%)
Overall Incidence	Total	0/245 (0%)	Mean 0% SD 0%	Total 1/193 (0.52%) Mean 0.53% SD 1.06%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma	• • • • • • • • • • • • • • • • • • • •			
		2/50 (4%) 0/47 (0%)	0/50 (0%) 0/50 (0%) 0/48 (0%)	0/49 (0%)
Overall Incidence	Total	2/245 (0.82%)	Mean 0.8% SD 1.79%	Total 3/193 (1.55%) Mean 1.6% SD 2.04%
#Tissue NOS: Lipoma				
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%
#Tissue NOS: Paraganglioma				
		0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	1/50 (2%) Mean 0.4% SD 0.89%	0/50 (0%) 0/50 (0%) Total 0/200 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 249

			Male				Female	
Tissue NOS: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Tongue: Squamous Cell Carcinoma								
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma o	or Papillon	na Squamous 1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)		1/50 (2%)
		0/50 (0%)	1/50 (2%)	,		0/50 (0%)	0/50 (0%)	,
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Tongue: Squamous Cell Papilloma								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/250 (1.2%)	Mean 1.2%	SD 1.1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Tooth: Adamantinoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

III. May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 250

			Male		Female
Tooth: Odontoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/200 (0%)	0/50 (0%) Mean 0% SD 0%
Jrinary Bladder: Carcinoma					
		0/50 (0%) 0/49 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%)	Mean 0% SD 0%	Total 0/199 (0%)	0/50 (0%) Mean 0% SD 0%
Urinary Bladder: Carcinoma or Papilloma					
		0/50 (0%) 0/49 (0%)	1/49 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
overall Incidence	Total	1/248 (0.4%)	Mean 0.41% SD 0.91%	Total 0/199 (0%)	Mean 0% SD 0%
Jrinary Bladder: Hemangiosarcoma					
		0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
hanall lundanaa	Tatal	0/49 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)
verall Incidence	Total	0/248 (0%)	Mean 0% SD 0%	Total 0/199 (0%)	Mean 0% SD 0%
Urinary Bladder: Leiomyosarcoma		0(50 (00))	2/12 (22)	272 (201)	272
		0/50 (0%) 0/49 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/43 (0%)	Mean 0% SD 0%	Total 0/199 (0%)	Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			Male				Female	
*Urinary Bladder: Papilloma		0/50 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)		0/50 (0%)
Overall Incidence	Total	0/49 (0%) 1/248 (0.4%)	0/50 (0%) Mean 0.41%	SD 0.91%	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Adenoma						0/50 (0%)		0/50 (0%)
Overall Incidence					Total	0/50 (0%) 1/200 (0.5%)	1/50 (2%) Mean 0.5%	SD 1%
#Uterus: Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Deciduoma Benign					•••••			
Overall Incidence					Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Hemangioma								
Overall Incidence					Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
						• •		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Page: 252

Report Date: 04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Male **Female** #Uterus: Hemangiosarcoma (0%)(0%)(0%) 0/50 0/50 (0%)Mean 0% **Overall Incidence** Total 0/200 (0%) SD 0% #Uterus: Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Uterus: Leiomyosarcoma (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 1% Total 1/200 (0.5%)Mean 0.5% **#Uterus: Polyp Stromal** (28%)(20%)(32%)(20%)**Overall Incidence** Mean 25% SD 6% Total 50/200 (25%) **#Uterus:** Sarcoma Stromal (0%) 0/50 1/50 (2%)0/50 (0%)

.....

Total

1/200

(0.5%)

Mean 0.5%

SD 1%

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Sarcoma Stromal or Polyp Stromal (20%)(28%)(34%) 17/50 10/50 (20%)**Overall Incidence** Total 51/200 (25.5%) Mean 25.5% SD 6.81% #Uterus: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Vagina: Polyp 0/50 (0%)0/50 (0%)0/50 (0%)0/50 **Overall Incidence** SD 0% Total 0/200 (0%) Mean 0% #Vagina: Sarcoma (0%) (0%)0/50 0/50 (0%)(0%)**Overall Incidence** SD 0% Total 0/200 (0%) Mean 0% #Zymbal's Gland: Adenoma (0%)(0%)0/50 0/50 0/50 0/50 (0%)(0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%)Mean 0% SD 0% Total 0/200 (0%)Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Zymbal's Gland: Carcinoma								
Carcinoma		0/50 (0%) 3/50 (6%)	1/50 (2%) 0/5 0/50 (0%)	0 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/250 (1.6%)	` '	SD 2.61%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%) 3/50 (6%)	1/50 (2%) 0/5 0/50 (0%)	0 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/250 (1.6%)	` ,	SD 2.61%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 255

Report Date:04/29/2009

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Southern Research Institute Southern Research Institute Southern Research Institute Southern Research Institute	052011407 059601905 059601705 059601505	10/02/02 09/26/01 03/08/00 09/05/01	730 729 729 729	50 (3) 50 (3) 50 (3) 50 (3)	28(696) 31(686) 34(683) 31(692)	532.4 526.0 522.9 507.8	Sodium dichromate dihydrate (VI) Water disinfection byproducts (Bromochloroacetic acid) Water disinfection byproducts (Dibromoacetic acid) Water disinfection byproducts (Dibromoacetonitrile)
				Fen	nale		
Southern Research Institute Southern Research Institute Southern Research Institute Southern Research Institute	052011407 059601905 059601705 059601505	10/02/02 09/26/01 03/08/00 09/05/01	735 731 734 734	50 (5) 50 (5) 50 (5) 50 (5)	33(700) 34(688) 35(693) 29(689)	351.2 357.3 350.5 337.6	Sodium dichromate dihydrate (VI) Water disinfection byproducts (Bromochloroacetic acid) Water disinfection byproducts (Dibromoacetic acid) Water disinfection byproducts (Dibromoacetonitrile)

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Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 256

			Male				Female	
#All Organs: Benign Tumors								
		49/50 (98%) 50/50 (100%)	50/50 (100%)	47/50 (94%)		47/50 (94%) 44/50 (88%)	49/50 (98%)	42/50 (84%)
Overall Incidence	Total	196/200 (98%)	Mean 98%	SD 2.83%	Total	182/200 (91%)	Mean 91%	SD 6.22%
#All Organs: Malignant Tumors								
-		29/50 (58%) 27/50 (54%)	27/50 (54%)	29/50 (58%)		20/50 (40%) 20/50 (40%)	18/50 (36%)	16/50 (32%)
Overall Incidence	Total	112/200 (56%)	Mean 56%	SD 2.31%	Total	74/200 (37%)	Mean 37%	SD 3.83%
#All Organs: Malignant and Benign 1								
		50/50 (100%) 50/50 (100%)	50/50 (100%)	50/50 (100%)		49/50 (98%) 48/50 (96%)	49/50 (98%)	45/50 (90%)
Overall Incidence	Total	200/200 (100%)	Mean 100%	SD 0%	Total	191/200 (95.5%)	Mean 95.5%	SD 3.79%
#All Organs: Hemangioma								
· ·		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #All Organs: Hemangiosarcoma or Hemangioma 1/50 (2%)0/50 (0%)(2%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 1/50 (2%)2/200 (1%) **Overall Incidence** Total Mean 1% SD 1.15% Total 1/200 (0.5%) Mean 0.5% SD 1% #All Organs: **Histiocytic Sarcoma** 0/50 (0%)0/50 (0%)0/50 (0%)(2%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/200 (1%) Mean 1% SD 2% Total 1/200 (0.5%) Mean 0.5% SD 1% #All Organs: Leukemia: Erythrocytic 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/200 (0%) Mean 0% Total 0/200 (0%) Mean 0% #All Organs: Leukemia: Lymphocytic, Monocytic, Mononuclear, or Undifferentiated 26/50 (52%)21/50 (42%)17/50 (34%)8/50 (16%)15/50 (30%)11/50 (22%)21/50 (42%)14/50 (28%)**Overall Incidence** 85/200 (42.5%) SD 7.37% 48/200 (24%) Total Mean 42.5% Total Mean 24% SD 6.32% **#All Organs:** Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** 0/200 (0%) SD 0% Mean 0.5% SD 1% Total Mean 0% Total 1/200 (0.5%)

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: RATS Strain: F344 Route: ORAL Vehicle: WATER

			Male				Female	
All Organs: Mesothelioma: Benign								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Benign, Ma								
.	g ,	2/50 (4%) 0/50 (0%)	1/50 (2%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	6/200 (3%)	Mean 3%	SD 2.58%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Malignant	•••••				•••••			
•		2/50 (4%) 0/50 (0%)	1/50 (2%)	3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	6/200 (3%)	Mean 3%	SD 2.58%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Species: RATS Strain: F344 Route: ORAL Vehicle: WATER

			Male				Female	
All Organs: Osteosarcoma or Osteoma		0/50 /00/	0/50 /00/	0/50 (00/)		0/50 /00/	4/50 (20/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Adrenal Cortex: Adenoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%
Adrenal Cortex: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
drenal Medulla: Ganglioneuroma								
v		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Hemangioma								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male				Female	
*Adrenal Medulla: Pheochromocytoma Bei	nign							
	_	6/49 (12%) 10/50 (20%)	9/50 (18%)	7/49 (14%)		2/49 (4%) 1/49 (2%)	2/49 (4%)	1/49 (2%)
Overall Incidence	Total	32/198 (16.16%)	Mean 16.13%	SD 3.51%	Total	6/196 (3.06%)	Mean 3.06%	SD 1.18%
*Adrenal Medulla: Pheochromocytoma Co							•••••	
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Ma								
·		1/49 (2%) 0/50 (0%)	1/50 (2%)	0/49 (0%)		1/49 (2%) 0/49 (0%)	2/49 (4%)	0/49 (0%)
Overall Incidence	Total	2/198 (1.01%)	Mean 1.01%	SD 1.17%	Total	3/196 (1.53%)	Mean 1.53%	SD 1.95%
Adrenal Medulla:	mian Complex	Malianant NOS						
Pheochromocytoma: Be	ingn, complex	7/49 (14%) 10/50 (20%)	10/50 (20%)	7/49 (14%)		3/49 (6%) 1/49 (2%)	4/49 (8%)	1/49 (2%)
Overall Incidence	Total	34/198 (17.17%)	Mean 17.14%	SD 3.3%	Total	9/196 (4.59%)	Mean 4.59%	SD 3.06%
#Bone: Chondrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 261

			Male				Female	
Bone: Chondrosarcoma or Chondr	oma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Bone: Chordoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Bone: Osteosarcoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Bone: Osteosarcoma or Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Brain: Astrocytoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Ependymoma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Ependymoma Malignant	•••••							
. ,		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Glioma Malignant							•••••	
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Granular Cell Tumor Benigi								
g.		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 263

			Male				Female	
Brain: Medulloblastoma Mal		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	,	,		0/50 (0%)	,	,
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Brain: Meningioma: Benign, Mali	gnant, NOS	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Brain: Oligodendroglioma Benig	n							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Maligr								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Species: RATS Strain: F344 Route: ORAL Vehicle: WATER

			Male				Female	
Brain:								
Oligodendroglioma, Gli	ioma, or Astroc	•						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Osteosarcoma	•••••		•••••			•••••		•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Schwannoma Malignan	nt							
· ·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma	•••••							
		4/50 (8%) 1/48 (2%)	4/50 (8%)	3/50 (6%)		2/50 (4%) 5/50 (10%)	17/50 (34%)	8/50 (16%)
Overall Incidence	Total	12/198 (6.06%)	Mean 6.02%	SD 2.79%	Total	32/200 (16%)	Mean 16%	SD 12.96%
Clitoral/Preputial Gland: Carcinoma	•••••							
		1/50 (2%) 0/48 (0%)	2/50 (4%)	0/50 (0%)		8/50 (16%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/198 (1.52%)	Mean 1.5%	SD 1.91%	Total	10/200 (5%)	Mean 5%	SD 7.39%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

on. May 2000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 265

			Male				Female	
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		4/50 (8%) 1/48 (2%)	5/50 (10%)	3/50 (6%)		10/50 (20%) 6/50 (12%)	17/50 (34%)	9/50 (18%)
verall Incidence	Total	13/198 (6.57%)	Mean 6.52%	SD 3.38%	Total	42/200 (21%)	Mean 21%	SD 9.31%
Clitoral/Preputial Gland: Fibrosarcoma								
		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Sarcoma					•••••			
		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Squamous Cell Papilloma				•••••				
		0/50 (0%) 0/48 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/198 (0.51%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Ear: Neural Crest Tumor								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Esophagus: Fibrosarcoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Esophagus: Lipoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Eye: Amelanotic Melanoma, Ben		0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Eye: Melanoma Malignant Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Eye: Schwannoma Malignant		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: ORAL Vehicle: WATER

			Male				Female	
#Harderian Gland: Carcinoma		0/50 (00)	(00)	2/72 (224)		2/20 (20)	2/22 (22)	2/72 (221)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Benign				•••••				
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%
*Heart: Schwannoma Malignant					•••••			
· ·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Large: Colon/Rectur								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 268

			Male				Female	
#Intestine Large: Colon/Re Carcinoma	ctum:							
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Large: Colon/Re Carcinoma or Adenoma	ctum:					•••••		
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Large: Colon/Re Hemangioma					•••••			
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenui Carcinoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenui Leiomyoma						•••••		
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incider

Species: RATS
Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 269

			Male				Female	
#Intestine Small: Jejunum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Granular Cell Tumor Ma							•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyoma					•••••			
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma					•••••			
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Intestine Small: Site Unsp Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: RATS Strain: F344

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male				Female	
Intestine Small: Site Unsp Carcinoma or Adenom								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unsp Granular Cell Tumor M								
	_	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unsp Leiomyoma	pecified:				•••••			
,		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
ntestine Small: Site Unsp Leiomyosarcoma	pecified:							
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
slets, Pancreatic: Adenoma					•••••			
		4/50 (8%) 5/49 (10%)	3/50 (6%)	5/48 (10%)		2/50 (4%) 1/50 (2%)	3/49 (6%)	0/47 (0%)
Overall Incidence	Total	17/197 (8.63%)	Mean 8.66%	SD 2.08%	Total	6/196 (3.06%)	Mean 3.03%	SD 2.63%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Islets, Pancreatic: Carcinoma 0/50 (0%)(4%)(0%)0/50 (0%)0/49 (0%)(0%)(0%)1/49 (2%)0/50 **Overall Incidence** Total 3/197 (1.52%) Mean 1.51% SD 1.92% Total 0/196 (0%) Mean 0% SD 0% *Islets. Pancreatic: Carcinoma or Adenoma 4/50 (8%)(10%)(10%)2/50 (4%)(0%)6/49 (12%)1/50 (2%)**Overall Incidence** Total 20/197 (10.15%) Mean 10.17% SD 1.74% Total 6/196 (3.06%) Mean 3.03% SD 2.63% *Kidney: Pelvis and Transitional Epithelium: Carcinoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/49 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/198 (0%) Mean 0% Total 0/200 (0%) Mean 0% *Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** 0/198 (0%) SD 0% SD 0% Total Mean 0% Total 0/200 (0%) Mean 0% *Kidney: Pelvis and Transitional Epithelium: **Papilloma** 0/50 (0%)0/50 (0%)0/49 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/198 (0%)Mean 0% SD 0% Total 0/200 (0%)Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

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			Male				Female	
Kidney: Renal Tubule: Adenoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Kidney: Renal Tubule: Carcinoma			•••••					•••••
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma			•••••					•••••
		0/50 (0%) 0/49 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Lipoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

1. Way2000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Report Date:04/29/2009

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			Male				Female	
*Kidney: Renal Tubule: Mesenchymal Tumor Ber	nign							
-		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Nephroblastoma	•••••							
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Sarcoma	•••••				•••••			
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Cholangioma	•••••				•••••			
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Liver: Hemangiosarcoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

d Control Animal Groups Report Date:04/29/2009
RAL

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			Male				Female	
*Liver: Hepatocellular Adenoma								
		0/50 (0%) 0/50 (0%)	2/50 (4%)	1/50 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
*Liver: Hepatocellular Carcinoma	1	•••••			•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma	or Hepatob	lastoma 0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Carcinoma	or Hepatoc	0/50 (0%)	2/50 (4%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/50 (0%) 3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/50 (0%) 3/200 (1.5%)	Mean 1.5%	SD 1.91%
*Liver: Hepatocellular Carcinoma Hepatoblastoma	a, Hepatocell	ular Adenoma, or						
···opatooiaotoiiia		0/50 (0%) 0/50 (0%)	2/50 (4%)	1/50 (2%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Lung: Alveolar/Bronchiolar Adenoma 4/50 (8%)(4%)(4%)4/50 (8%)(2%)(2%)(6%)3/50 1/50 (2%)**Overall Incidence** Total 11/200 (5.5%) Mean 5.5% SD 1.91% Total 7/200 (3.5%) Mean 3.5% SD 3% *Lung: Alveolar/Bronchiolar Carcinoma 0/50 (0%)(0%)0/50 (0%)0/50 (0%)(2%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 2/200 (1%) SD 1.15% Total Mean 0.5% SD 1% Mean 1% 1/200 (0.5%) *Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma (8%)3/50 (4%)4/50 (8%)1/50 2/50 (4%)(8%) (2%) 4/50 1/50 **Overall Incidence** Total 13/200 (6.5%) SD 1.91% 8/200 (4%) SD 2.83% Mean 6.5% Total Mean 4% *Lung: Fibrosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)SD 0% 0/200 (0%) SD 0% **Overall Incidence** Total 0/200 (0%) Mean 0% Total Mean 0% *Lung: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Lung: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
*Lung: Squamous Cell Carcinoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangiosarcoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenolipoma	•••••				•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 2%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Species: RATS Strain: F344 Route: ORAL Vehicle: WATER

			Male				Female	
Mammary Gland: Carcinoma								
		1/50 (2%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 2/50 (4%)	1/50 (2%)	3/50 (6%)
verall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	6/200 (3%)	Mean 3%	SD 2.58%
Mammary Gland: Carcinoma or Adenoma							•••••	
		1/50 (2%) 1/50 (2%)	0/50 (0%)	1/50 (2%)		2/50 (4%) 2/50 (4%)	1/50 (2%)	3/50 (6%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1%	Total	8/200 (4%)	Mean 4%	SD 1.63%
Mammary Gland: Fibroadenoma								
		2/50 (4%) 6/50 (12%)	3/50 (6%)	4/50 (8%)		37/50 (74%) 31/50 (62%)	43/50 (86%)	32/50 (64%)
overall Incidence	Total	15/200 (7.5%)	Mean 7.5%	SD 3.42%	Total	143/200 (71.5%)	Mean 71.5%	SD 11%
Mammary Gland: Fibroma						•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenoma or								
		2/50 (4%) 6/50 (12%)	3/50 (6%)	4/50 (8%)		37/50 (74%) 31/50 (62%)	43/50 (86%)	32/50 (64%)
Overall Incidence	Total	15/200 (7.5%)	Mean 7.5%	SD 3.42%	Total	143/200 (71.5%)	Mean 71.5%	SD 11%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

(0%)

(0%)

(0.5%)

0/50

(0%)

Mean 0.5%

0/50

0/50

1/200

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male Female #Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma (6%)(6%)(10%)(74%)(86%)(64%)6/50 (12%)31/50 (62%)**Overall Incidence** 17/200 (8.5%) Mean 8.5% SD 3% Total 143/200 (71.5%) Mean 71.5% SD 11% Total #Mesentery: Fibrosarcoma 0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% Total #Mesentery: Hemangiosarcoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/200 (0%) Mean 0% Total 0/200 (0%) Mean 0% #Mesentery: Lipoma 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/200 (0%) SD 0% SD 0% Total Mean 0% Total 0/200 (0%) Mean 0% #Mesentery:

SD 1%

0/50

0/50

0/200

Total

(0%)

(0%)

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

Rhabdomyosarcoma

Overall Incidence

Page: 278

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Vehicle: WATER

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Report Date:04/29/2009

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Species: RATS Strain: F344

Length of Study: CHRONIC

			Male	Female
*Nose: Adenoma		0/50 (00/)	0/50 (00/) 0/40 (00/)	0/50 (00) 0/50 (00)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%
*Nose: Chondroma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%
*Nose: Squamous Cell Carcinor	 ma			
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%
#Oral Cavity (Oral Mucosa, 7 Papilloma Squamous or	Tongue, Phary			
	·	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%) 0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 3/200 (1.5%) Mean 1.5% SD 1%
#Oral Cavity (Oral Mucosa, 7 Squamous Cell Carcinor		nx, Tooth, Gingiva):		
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0% SD 0%	Total 0/200 (0%) Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 280

Mean 0%

SD 0%

Report Date: 04/29/2009

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or **Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)1/50 1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** SD 0% 3/200 (1.5%) Mean 1.5% SD 1% Total 0/200 (0%) Mean 0% Total **#Oral Mucosa:** Squamous Cell Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) (0%)0/50 0/50 0/200 (0%) SD 0% 0/200 (0%) SD 0% Overall Incidence Total Mean 0% Total Mean 0% **#Oral Mucosa: Squamous Cell Papilloma** (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)(0%) (0%) 0/50 0/50 **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% *Ovary: Cystadenoma 0/49 0/50 (0%)0/50 (0%)0/50 (0%)SD 0% **Overall Incidence** Total 0/199 (0%) Mean 0% *Ovary: **Granulosa Cell Tumor Benign** 0/490/50 (0%)0/50 (0%)0/50 (0%)

Total

0/199 (0%)

Overall Incidence

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

	Male			Female	
*Ovary:					
Granulosa Cell Tumor Malignant			0/49 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)		00.00
Overall Incidence		Total	0/199 (0%)	Mean 0%	SD 0%
*Ovary:					
Granulosa Cell Tumor: Benign, Malignant, NOS			0/40 (00/)	0/50 (00/)	0/50 (00/)
			0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/199 (0%)	Mean 0%	SD 0%
*Ovary:					
Granulosa-Theca Tumor Benign					
<u>-</u>			0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	1/50 (2%) 1/199 (0.5%)	Mean 0.5%	SD 1%
*Ovary:					
Granulosa-Theca Tumor Malignant			0/49 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	(676)	(0,0)
Overall Incidence		Total	0/199 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma					
i abaiosii oiliai Auctioilia			0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/50 (0%)	Maan 00/	CD 00/
Overall incidence		Total	0/199 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 282

			Male				Female	
Pancreas: Adenoma		1/50 (2%)	2/50 (4%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/47 (0%)
		1/49 (2%)	2/30 (4%)	0/46 (0%)		0/50 (0%)	0/30 (0%)	0/47 (0%)
Overall Incidence	Total	4/197 (2.03%)	Mean 2.01%	SD 1.63%	Total	0/197 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma								
		1/50 (2%) 1/49 (2%)	2/50 (4%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	4/197 (2.03%)	Mean 2.01%	SD 1.63%	Total	0/197 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Benign								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Malignant								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 283

			Male				Female	
Parathyroid Gland: Adenoma								
		0/46 (0%) 1/46 (2%)	0/44 (0%)	0/50 (0%)		0/46 (0%) 0/42 (0%)	0/42 (0%)	0/50 (0%)
Overall Incidence	Total	1/186 (0.54%)	Mean 0.54%	SD 1.09%	Total	0/180 (0%)	Mean 0%	SD 0%
Peripheral Nerve: Schwannoma Malignant			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Peripheral Nerve: Schwannoma: Benign, Ma	lignant, NOS	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distalis Adenoma								
		16/50 (32%) 24/50 (48%)	23/48 (48%)	23/50 (46%)		28/50 (56%) 27/49 (55%)	28/50 (56%)	26/50 (52%)
Overall Incidence	Total	86/198 (43.43%)	Mean 43.48%	SD 7.71%	Total	109/199 (54.77%)	Mean 54.78%	SD 1.9%
Pituitary Gland: Pars Distalis Carcinoma					•••••			
		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		2/50 (4%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	2/199 (1.01%)	Mean 1%	SD 2%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: RATS Strain: F344

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male				Female	
Pituitary Gland: Pars Dista Carcinoma or Adenoma								
		16/50 (32%) 24/50 (48%)	23/48 (48%)	23/50 (46%)		30/50 (60%) 27/49 (55%)	28/50 (56%)	26/50 (52%)
Overall Incidence	Total	86/198 (43.43%)	Mean 43.48%	SD 7.71%	Total	111/199 (55.78%)	Mean 55.78%	SD 3.3%
Pituitary Gland: Pars Dista Ganglioneuroma	lis or Unspecif	ied Site:						
-		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Interr Adenoma	media:							
		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Pituitary Gland: Pars Interr Carcinoma	media:							
		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Interr Carcinoma or Adenoma	media:							
		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Toxicology Data Management System

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 285

			Male				Female	
Prostate:								
		2/50 (4%) 0/49 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%				
Prostate: Carcinoma or Adenoma								
		2/50 (4%) 0/49 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%				
Salivary Glands: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				
Skeletal Muscle: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

			Male				Female	
Skeletal Muscle: Hemangioma								
ū		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Lipoma	•••••							
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma						•••••	•••••	
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or I						•••••		
,		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: RATS Strain: F344

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male				Female	
Skeletal Muscle: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Adenoma							•••••	
		2/50 (4%) 2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.31%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Adenoma or B Overall Incidence	Basosquamou Total	s Tumor Benign 2/50 (4%) 2/50 (4%) 4/200 (2%)	0/50 (0%) Mean 2%	0/50 (0%) SD 2.31%	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Basal Cell Adenoma, Bas Trichoepithelioma						,		
·		2/50 (4%) 2/50 (4%)	3/50 (6%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	8/200 (4%)	Mean 4%	SD 1.63%	Total	0/200 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma								
		0/50 (0%) 2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

				Male						Fema	ie		
Skin: Basal Cell Carcinoma NOS)	or Basosquamo	us Tumor (mal	lignant or										
1100)			0%) 4%))/50 (0%)) 1/50	(2%)		0/50 0/50	(0%) (0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	3/200 (1.5	,	Mean 1.5		1.91%	Total	0/200	` ,	Mean		SD	
#Skin: Basal Cell Carcinoma, Tumor (benign, maligr	Basal Cell Ader	noma, Basosqu Trichoepithelio	uamous oma	3/50 (6%		(4%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		4/50 (8%)́		,	,		0/50	(0%)		,		,
Overall Incidence	Total	11/200 (5.	5%)	Mean 5.5	% SD	1.91%	Total	0/200	(0%)	Mean	0%	SD	0%
#Skin: Basal or Sq. Cell Carci or B), Basal Cell Aden Papilloma, Keratoacan	oma, Adenoma,	Papilloma, Sq pithelioma	•	NEO (400	() 7/50	(4.40/.)		4/50	(20()	0/50	(00()	4/50	(20()
Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan	oma, Ådenoma, nthoma, Trichoe	Papilloma, Sq pithelioma 5/50 (11/50 (10%) 6 22%)	6/50 (12%	,	(14%)	Total	1/50 0/50	(2%) (0%)	0/50 Maga	(0%)	1/50	(2%)
Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence	oma, Ådenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 5/50 (11/50 (; 29/200 (14	10%) 6 22%) 4.5%)	Mean 14.	5% SD	5.26%	Total	0/50 2/200	(0%) (1%)	Mean	1%	SD	1.15%
Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence	oma, Ådenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 5/50 (11/50 (29/200 (14	10%) 6 22%) 4.5%)	Mean 14.	5% SD	5.26%		0/50 2/200	(0%) (1%)	Mean	1%	SD	1.15%
Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence	oma, Ådenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 5/50 (11/50 (29/200 (14	10%) 6 22%) 4.5%)	Mean 14.	5% SD	5.26%		0/50 2/200	(0%) (1%)	Mean	1%	SD	1.15%
Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence #Skin: Fibroma	oma, Ádenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 5/50 (11/50 (3 29/200 (14 8/50 (8/50 (28/200 (14	10%) 6 22%) 4.5%)	Mean 14.4 7/50 (14% Mean 14%	5% SD 6) 5/50 6 SD	5.26% (10%) 2.83%	Total	0/50 2/200 1/50 0/50 3/200	(0%) (1%) (2%) (0%) (1.5%)	Mean 1/50 Mean	1% (2%) 1.5%	1/50 SD	1.15% (2%) 1%
or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence *Skin: Fibroma	oma, Ádenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 5/50 (11/50 (29/200 (14 8/50 (8/50 (28/200 (14	10%) 6 22%) 4.5%)	Mean 14.4 7/50 (14% Mean 14%	5% SD 6) 5/50 6 SD	5.26% (10%) 2.83%	Total	0/50 2/200 1/50 0/50 3/200	(0%) (1%) (2%) (0%) (1.5%)	Mean 1/50 Mean	1% (2%) 1.5%	1/50 SD	1.15% (2%) 1%
Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence #Skin: Fibroma Overall Incidence #Skin: Fibroma	oma, Ádenoma, nthoma, Trichoe Total	Papilloma, Sq pithelioma 5/50 (11/50 (; 29/200 (14 	10%) 6 22%) 4.5%) 16%) 7 16%) 4%)	Mean 14.4 7/50 (14% Mean 14%	5% SD (6) 5/50 (6 SD	5.26% (10%) 2.83%	Total	0/50 2/200 1/50 0/50 3/200	(0%) (1%) (2%) (0%) (1.5%)	Mean 1/50 Mean	1% (2%) 1.5%	1/50 SD	1.15% (2%) 1%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

I Animal Groups Report Date:04/29/2009

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			Male				Female	
#Skin: Fibrosarcoma								
		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Fibrosarcoma, Sarcoma Histiocytoma								
Histocytoma		3/50 (6%) 1/50 (2%)	1/50 (2%)	1/50 (2%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/200 (3%)	Mean 3%	SD 2%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Fibrous Histiocytoma			- 1 1					
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Hemangioma		(22)	(201)	(00)		0/20 (00)	(00)	2/22 (22)
		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Species: RATS

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male				Female	
#Skin: Keratoacanthoma								
		2/50 (4%) 6/50 (12%)	1/50 (2%)	3/50 (6%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	12/200 (6%)	Mean 6%	SD 4.32%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Lipoma	•••••				•••••			
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma								
·		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor	•••••				•••••			
		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor, Malign	nant							
, •		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

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^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Neurofibroma or Schwannoma benign 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS) 0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) #Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%) 0/50 0/50 **Overall Incidence** Total 0/200 (0%) SD 0% Total 0/200 (0%) SD 0% Mean 0% Mean 0% #Skin: Sarcoma 2/50 (4%)0/50 (0%)1/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 3/200 (1.5%) Mean 1.5% SD 1.91% Total 0/200 (0%) Mean 0% SD 0% #Skin: Schwannoma Benign 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 292 Report Date: 04/29/2009

Species: RATS Strain: F344 Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Skin: Schwannoma Malignant		0/50 (00)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinom	a							
		1/50 (2%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinom Basosquamous Tumor (n			0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papilloma	· · · · · · · · · · · · · · · · · · ·					•••••		
		1/50 (2%) 1/50 (2%)	3/50 (6%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	7/200 (3.5%)	Mean 3.5%	SD 1.91%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Squamous Cell Papilloma	or Papillom	a						
•	-	1/50 (2%) 1/50 (2%)	3/50 (6%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/30 (2/0)						

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma (8%)4/50 (8%)(12%)0/50 (0%)1/50 (2%)7/50 (14%)0/50 (0%)**Overall Incidence** 21/200 (10.5%) SD 1.15% Total Mean 10.5% SD 3% Total 2/200 (1%) Mean 1% Squamous Cell Papilloma, Papilloma, or Keratoacanthoma 3/50 4/50 (8%)(10%)1/50 (2%)0/50 1/50 (2%)7/50 (14%)0/50 (0%)19/200 (9.5%) SD 1.15% **Overall Incidence** Total Mean 9.5% SD 3.42% Total 2/200 (1%) Mean 1% #Skin: Trichoepithelioma 0/50 (0%)3/50 1/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%) 0/50 0/50 **Overall Incidence** Total 4/200 (2%) SD 2.83% 0/200 (0%) SD 0% Mean 2% Total Mean 0% #Skin: Sebaceous Gland: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/200 (0.5%) **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total Mean 0.5% SD 1% #Skin: Sebaceous Gland: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 294

			Male				Female	
Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Spinal Cord: Astrocytoma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spinal Cord: Astrocytoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spinal Cord: Glioma Malignant								•••••
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Spleen: Fibrosarcoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 295

			Male				Female	
*Spleen: Fibrous Histiocytoma		2/22 (221)		2(72 (22))		2/22 (221)		2/1- /22/
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma								
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma								
ŭ		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
*Spleen: Leiomyosarcoma					•••••			
,		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%
*Spleen: Sarcoma	•••••							
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 296 Report Date:04/29/2009

			Male				Female	
Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma c Overall Incidence	r Papillon Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	1/50 (2%) SD 1%	Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	1/50 (2%) SD 1%
Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Stomach, Glandular: Lipoma							- 1	
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 297

			Male				Female	
#Stomach, Glandular: Sarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Testes: Adenoma								
Overall Incidence	Total	48/50 (96%) 49/50 (98%) 184/200 (92%)	46/50 (92%) Mean 92%	41/50 (82%) SD 7.12%				
		,						
*Thymus: Sarcoma								
		0/48 (0%) 0/43 (0%)	0/49 (0%)	1/49 (2%)		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/189 (0.53%)	Mean 0.51%	SD 1.02%	Total	0/197 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign								
		0/48 (0%) 0/43 (0%)	0/49 (0%)	1/49 (2%)		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/189 (0.53%)	Mean 0.51%	SD 1.02%	Total	0/197 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
		0/48 (0%) 0/43 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%) 0/48 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/189 (0%)	Mean 0%	SD 0%	Total	0/197 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male Female *Thymus: Thymoma NOS 0/48 (0%)0/49 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/43 (0%)0/48 (0%)Mean 0% 0/197 (0%) **Overall Incidence** Total 0/189 (0%) SD 0% Total Mean 0% SD 0% *Thymus: Thymoma: Benign, Malignant, NOS 0/48 (0%)0/50 (0%)(0%)0/43 (0%)0/48 (0%)**Overall Incidence** Total Mean 0.51% SD 1.02% Total 0/197 (0%) Mean 0% SD 0% 1/189 (0.53%) *Thyroid Gland: C-Cell: Adenoma 5/50 (10%)(6%)(12%)8/50 (16%)(12%)(12%)10/49 (20%)6/46 (13%) **Overall Incidence** SD 6.07% Total 24/199 (12.06%) Mean 12.1% Total 26/195 (13.33%) Mean 13.32% SD 1.84% *Thyroid Gland: C-Cell: Carcinoma 1/50 (2%)2/50 (4%)(2%)0/50 (0%)1/49 (2%)0/46 (0%)**Overall Incidence** 4/199 (2.01%) Mean 2.01% SD 0.02% 3/195 (1.54%) SD 1.92% Total Total Mean 1.51% *Thyroid Gland: C-Cell: Carcinoma or Adenoma (12%)6/50 (8%)(14%)10/50 (20%)7/49 (14%)(12%)11/49 (22%)6/46 (13%)**Overall Incidence** Total 28/199 (14.07%) Mean 14.11% SD 6.09% Total 29/195 (14.87%) Mean 14.83% SD 3.57%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories Species: RATS

Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 299

			Male				Female	
Thyroid Gland: Follicular Cell: Adenoma								
		0/50 (0%) 0/49 (0%)	2/50 (4%)	1/50 (2%)		0/50 (0%) 1/46 (2%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%	Total	1/195 (0.51%)	Mean 0.54%	SD 1.09%
Thyroid Gland: Follicular Cell: Carcinoma								•••••
		0/50 (0%) 0/49 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/46 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/195 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		0/50 (0%) 0/49 (0%)	3/50 (6%)	1/50 (2%)		0/50 (0%) 1/46 (2%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2%	SD 2.83%	Total	1/195 (0.51%)	Mean 0.54%	SD 1.09%
Tissue NOS: Lipoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Tissue NOS: Paraganglioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: F344 Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 300

			Male				Female	
#Tissue NOS: Schwannoma Malignant								
_		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Carcinoma						•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma o	or Papillon	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%	Total	1/50 (2%) 2/200 (1%)	Mean 1%	SD 1.15%
Tongue: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Tooth: Adamantinoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Strain: F344 Length of Study: CHRONIC Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Female Male #Tooth: Odontoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 Mean 0% **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/200 (0%) SD 0% *Urinary Bladder: Carcinoma 0/50 (0%)(0%)(2%)0/49 (0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/199 (0%) Mean 0% SD 0% *Urinary Bladder: Carcinoma or Papilloma 0/50 (0%)0/50 (0%)(2%)0/49 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Mean 0.5% SD 1% SD 0% Total 1/200 (0.5%) Total 0/199 (0%) Mean 0% *Urinary Bladder: Hemangiosarcoma 0/50 (0%)0/49 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/200 (0%) SD 0% 0/199 (0%) Mean 0% SD 0% Total Mean 0% Total *Urinary Bladder: Leiomyosarcoma 0/50 (0%)(0%)0/49 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%)Mean 0% SD 0% Total 0/199 (0%)Mean 0% SD 0%

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^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** *Urinary Bladder: Papilloma 0/50 (0%)(0%)(0%)0/49 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/199 (0%) Mean 0% SD 0% #Uterus: Adenoma 1/50 (2%)(0%)(0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% #Uterus: Carcinoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%) **Overall Incidence** SD 0% Total 0/200 (0%) Mean 0% **#Uterus:** Deciduoma Benign 0/50 (0%) 0/50 (0%)0/50 0/50 (0%)**Overall Incidence** 0/200 (0%) Mean 0% SD 0% Total #Uterus: Hemangioma (0%) 0/50 (0%)0/50 0/50 (0%)**Overall Incidence** Total 0/200 (0%)Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 303

Report Date: 04/29/2009

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Hemangiosarcoma 0/50 (0%)(0%)(2%) 1/50 **Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% #Uterus: Leiomyoma 0/50 (0%)(0%)(0%)0/50 (0%) **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% #Uterus: Leiomyosarcoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%) **Overall Incidence** Mean 0% SD 0% Total 0/200 **#Uterus: Polyp Stromal** 10/50 (20%)(18%)(8%) 13/50 (26%)**Overall Incidence** 36/200 (18%) Mean 18% SD 7.48% Total **#Uterus:** Sarcoma Stromal (0%) 0/50 (0%)0/50 0/50 (0%)**Overall Incidence** Total 0/200 (0%)Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 304

Report Date: 04/29/2009

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Sarcoma Stromal or Polyp Stromal (20%)(18%)(8%) 13/50 (26%)**Overall Incidence** Total 36/200 (18%) Mean 18% SD 7.48% #Uterus: Schwannoma Malignant 0/50 (0%)(0%)(0%)1/50 (2%)**Overall Incidence** Total 1/200 (0.5%) Mean 0.5% SD 1% #Vagina: Polyp 0/50 (0%)0/50 (0%)(0%)0/50 (0%) **Overall Incidence** SD 0% Total 0/200 (0%) Mean 0% #Vagina: Sarcoma (0%) 0/50 0/50 (0%)0/50 0/50 (0%)**Overall Incidence** Mean 0% SD 0% Total 0/200 (0%) #Zymbal's Gland: Adenoma (0%)(0%)0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/200 (0.5%)Mean 0.5% SD 1% Total 0/200 (0%)Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

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			Male		0/50 (0%) Total 2/200 (1%) Mean 1% SD 1.15%			
#Zymbal's Gland: Carcinoma								
Garomonia		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 1/50 (2%)		
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	` ,	Mean 1% SD 1.15%		
#Zymbal's Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)		
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total 2/200 (1%)	Mean 1% SD 1.15%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

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Report Date:04/29/2009

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				M	ale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Southern Research Institute	059902805 059700307 059302007	09/16/02 07/10/02 04/24/00	729 728 729	50 (1) 50 (1) 50 (1)	21(676) 25(680) 20(670)	506.2 510.4 484.2	bis(2-Chloroethoxy)methane 1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide
				Fen	nale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Southern Research Institute	059902805 059700307 059302007	09/17/02 07/11/02 04/24/00	730 729 731	50 (1) 50 (1) 50 (1)	19(646) 29(695) 30(672)	341.0 337.8 319.5	bis(2-Chloroethoxy)methane 1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male				Female	
#All Organs: Benign Tumors								
-		49/50 (98%)	46/50 (92%)	47/50 (94%)		37/50 (74%)	46/50 (92%)	44/50 (88%)
Overall Incidence	Total	142/150 (94.67%)	Mean 94.67%	SD 3.06%	Total	127/150 (84.67%)	Mean 84.67%	SD 9.45%
#All Organs: Malignant Tumors		20/50 (529/)	22/50 (46%)	24/50 (000/)		40/50 (200/)	45/50 (200())	20/50 (448/)
Overall Incidence	Total	26/50 (52%) 83/150 (55.33%)	23/50 (46%) Mean 55.33%	34/50 (68%) SD 11.37%	Total	19/50 (38%) 56/150 (37.33%)	15/50 (30%) Mean 37.33%	22/50 (44%) SD 7.02%
		,				` ,		
#All Organs: Malignant and Benign Tu	umors							
Occupation of the second	T-1-1	49/50 (98%)	50/50 (100%)	50/50 (100%)	T-1-1	44/50 (88%)	48/50 (96%)	48/50 (96%)
Overall Incidence	Total	149/150 (99.33%)	Mean 99.33%	SD 1.15%	Total	140/150 (93.33%)	Mean 93.33%	SD 4.62%
#All Organs: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
			•••••		•••••			
#All Organs: Hemangiosarcoma								
3		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#All Organs: Hemangiosarcoma or He	emangioma							
-	-	1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
#All Organs: Histiocytic Sarcoma		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#All Organs: Leukemia: Erythrocytic		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic, N Undifferentiated	Monocytic, M	lononuclear, or			•••••			
Overall Incidence	Total	17/50 (34%) 47/150 (31.33%)	17/50 (34%) Mean 31.33%	13/50 (26%) SD 4.62%	Total	12/50 (24%) 31/150 (20.67%)	10/50 (20%) Mean 20.67%	9/50 (18%) SD 3.06%
#All Organs: Malignant Lymphoma: His or Undifferentiated Cell Ty	tiocytic, Lyn							
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#All Organs: Mesothelioma: Benign					•••••			
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#All Organs: Mesothelioma: Benign, Ma						0/50 (00/)	0/50 (00)	
Overall Incidence	Total	2/50 (4%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date:04/29/2009

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			Male				Female	
#All Organs: Mesothelioma: Malignant		2/50 (4%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma		0/50 /09/\	0/50 (0%)	0/50 (09/)		0/50 (0%)	0/50 /09/ \	0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#All Organs: Osteosarcoma or Osteoma	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Adenoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 3/150 (2%)	3/50 (6%) Mean 2%	0/50 (0%) SD 3.46%	Total	0/50 (0%) 3/150 (2%)	0/50 (0%) Mean 2%	3/50 (6%) SD 3.46%
*Adrenal Cortex: Carcinoma			- 1	- ()				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
*Adrenal Medulla: Ganglioneuroma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Adrenal Medulla: Hemangioma	•	0/50 (09/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/40 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Adrenal Medulla: Pheochromocytoma Beni	gn	2/50 (69/)	E/EO (400()	2/50 (69/)		1/50 (20/)	1/50 (29/)	0/40 (09/)
Overall Incidence	Total	3/50 (6%) 11/150 (7.33%)	5/50 (10%) Mean 7.33%	3/50 (6%) SD 2.31%	Total	1/50 (2%) 2/149 (1.34%)	1/50 (2%) Mean 1.33%	0/49 (0%) SD 1.15%
*Adrenal Medulla: Pheochromocytoma Com		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Mali	gnant							
Overall Incidence	Total	0/50 (0%) 4/150 (2.67%)	0/50 (0%) Mean 2.67%	4/50 (8%) SD 4.62%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Adrenal Medulla: Pheochromocytoma: Ben	ign, Comple		5/50 /400/	0/50 /400()		4/50 (00)	4/50 (00/)	0/40 (00/)
Overall Incidence	Total	3/50 (6%) 14/150 (9.33%)	5/50 (10%) Mean 9.33%	6/50 (12%) SD 3.06%	Total	1/50 (2%) 2/149 (1.34%)	1/50 (2%) Mean 1.33%	0/49 (0%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Toxicology Data Management System

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 311 Report Date:04/29/2009

			Male				Female	
#Bone: Chondrosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Bone: Chondrosarcoma or Cho	ondroma	0/50 (09/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Chordoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	0/50 (0%) SD 0%
#Bone: Osteoma		0/50 (00()	0/50 (00/)	0/50 (00()		0/50 (00()	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteosarcoma		(00)	(00)	0/50 (00)		(201)	0/20 (00)	2/22 (22)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteosarcoma or Osteo	oma	(204)		(201)			0/20 (00)	2/22 (22)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: ETHANOL

r Selected Control Animal Groups

Route: SKIN

Report Date:04/29/2009

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Species: RATS Strain: F344

Length of Study: CHRONIC

			Male	Female
*Brain: Astrocytoma Malignant	Tatal	0/50 (0%)	1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
*Brain: Ependymoma Benign		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	Total 0/150 (0%)
*Brain: Ependymoma Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Brain: Glioma Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Brain: Granular Cell Tumor Benigi	n	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Brain: Medulloblastoma Mal	••••	0/50 (09/)	0/50 (00/) 0/50 (00/)	0/50 (09/) 0/50 (09/) 0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

1. May2009

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

ol Animal Groups Report Date:04/29/2009

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			Male				Female	
*Brain: Meningioma Malignant								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Brain: Meningioma: Benign, Mal	lignant, NOS	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/30 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Brain: Oligodendroglioma Benig								0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Brain: Oligodendroglioma Malig	nant	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Brain: Oligodendroglioma, Glior	ma, or Astroc							
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
*Brain: Osteosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male	Fe	emale
*Brain: Schwannoma Malignant					
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 Total 0/150 (0%) M	0 (0%) 0/50 (0%) lean 0% SD 0%
*Clitoral/Preputial Gland: Adenoma					
Overall Incidence	Total	2/50 (4%) 5/150 (3.33%)	2/50 (4%) 1/50 (2%) Mean 3.33% SD 1.15%	2/50 (4%) 6/50 Total 10/150 (6.67%) M	0 (12%) 2/50 (4%) lean 6.67% SD 4.62%
*Clitoral/Preputial Gland: Carcinoma					
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) 1/50 (2%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 Total 2/150 (1.33%) M	0 (0%) 2/50 (4%) lean 1.33% SD 2.31%
*Clitoral/Preputial Gland: Carcinoma or Adenoma	••••	2/50 (4%)	2/50 (4%) 2/50 (4%)	2/50 (4%) 6/50) (12%) 4/50 (8%)
Overall Incidence	Total	6/150 (4%)	Mean 4% SD 0%	` ,	lean 8% SD 4%
*Clitoral/Preputial Gland: Fibrosarcoma	•••••			0/50 (0%) 0/50	(00/) 0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 Total 0/150 (0%) M	0 (0%) 0/50 (0%) lean 0% SD 0%
*Clitoral/Preputial Gland: Sarcoma					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 Total 0/150 (0%) M	0 (0%) 0/50 (0%) lean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Papilloma	1	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Ear: Neural Crest Tumor		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Esophagus: Fibrosarcoma		0/50 (0%)	0/50 (09/)	0/50 (09/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Esophagus: Lipoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		4/50 (00)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
Eye: Amelanotic Melanoma, Bo	enign							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Eye: Melanoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

r Selected Control Animal Group

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Report Date:04/29/2009

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Eye: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma		0/50 (09/)	0/50 (09/)	0/50 (0%)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Heart: Schwannoma Benign		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	0/50 (0%) SD 2.31%	Total	0/30 (0%)	Mean 0%	0/50 (0%) SD 0%
*Heart: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Intestine Large: Colon/Rectur Adenoma	n:							
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

d Control Animal Groups Report Date:04/29/2009 SKIN

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			Male	Female
#Intestine Large: Colon/Rectum: Carcinoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Intestine Large: Colon/Rectum: Carcinoma or Adenoma		0/50 (00()	0.50 (00)	4/50 (001) 4/50 (001) 0/50 (001)
Occupation of the sec	T-1-1	0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 2/150 (1.33%) Mean 1.33% SD 1.15%
#Intestine Large: Colon/Rectum: Hemangioma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Duodenum: Carcinoma				
	.	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Duodenum: Leiomyoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Jejunum: Carcinoma		0/50 (09/)	0/50 /0%) 0/50 /0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Insidence	Tatal	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Tatal 0/450 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male	Female
#Intestine Small: Jejunum: Granular Cell Tumor Malig	jnant			
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
·····			Widaii 6.0770 GD 1.1070	10tal 0/100 (070) INICAL 070 GD 070
#Intestine Small: Jejunum: Leiomyoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
			Widaii 070 GB 070	10tal 0/100 (070) INCAN 070 0D 070
#Intestine Small: Jejunum: Leiomyosarcoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
Overall incluence	TOLAI	0/130 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Weath 0% 3D 0%
#Intestine Small: Site Unspeci Carcinoma	ified:	0/50 (00/)	0/50 (00)	0/50 (00%) 0/50 (00%) 0/50 (00%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
		,		
#Intestine Small: Site Unspeci Carcinoma or Adenoma	ified:			
Overall Incidence	Total	0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
Overali incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Site Unspeci Granular Cell Tumor Malig				
Overell healthanes	Tatal	1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) T-t-1 0/450 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
Intestine Small: Site Unspecif Leiomyoma	fied:							
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspecif Leiomyosarcoma	fied:				•••••	•••••		•••••
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
slets, Pancreatic: Adenoma					•••••	•••••		•••••
		3/50 (6%)	6/50 (12%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	14/150 (9.33%)	Mean 9.33%	SD 3.06%	Total	0/150 (0%)	Mean 0%	SD 0%
slets, Pancreatic: Carcinoma					•••••	•••••		
		0/50 (0%)	0/50 (0%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
slets, Pancreatic: Carcinoma or Adenoma						•••••		•••••
		3/50 (6%)	6/50 (12%)	7/50 (14%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	16/150 (10.67%)	Mean 10.67%	SD 4.16%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
idney: Pelvis and Transition Carcinoma	al Epitheliu	m:			•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

				Ma	ale						Fem	ale	
*Kidney: Pelvis and Transitional Epithelium: Carcinoma or Adenoma													
			(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
	otal	0/150 (0	,	Mean		SD		Total	0/150	` ,		n 0%	SD 0%
Kidney: Pelvis and Transitional Ep Papilloma		n:											
			(0%)		(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
verall Incidence	otal	0/150 (0	%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mea	n 0%	SD 0%
(idney: Renal Tubule: Adenoma		0/50	(00()		(004)		(004)		0/-0	(00/)	0 /= 0	(004)	(00)
		0/50	(0%)		(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
	Total	1/150 (0.	,		0.67%		1.15%	Total	0/150	` ,		n 0%	SD 0%
idney: Renal Tubule: Carcinoma													
			(0%)		(0%)	0/50	(0%)	-	0/50	(0%)	0/50	(0%)	0/50 (0%)
verall Incidence	Total	0/150 (0	%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mea	n 0%	SD 0%
idney: Renal Tubule: Carcinoma or Adenoma													
			(0%)		(2%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50 (0%)
verall Incidence	otal	1/150 (0.	.67%)	Mean	0.67%	SD	1.15%	Total	0/150	(0%)	Mea	n 0%	SD 0%
idney: Renal Tubule: Hemangiosarcoma													
	-4-1	0/50	(0%)		(0%)	0/50	(0%)	Tatal	0/50	(0%)	0/50	(0%)	0/50 (0%)
verall Incidence	otal	0/150 (0	%)	Mean	υ%	SD	0%	Total	0/150	(0%)	Mea	n 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: SKIN Vehicle: ETHANOL

				Ma	ale						Fem	ale		
*Kidney: Renal Tubule: Lipoma														
		1/50	` ,		(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%	Total	0/150	(0%)	Mea	n 0%	SD	0%
*Kidney: Renal Tubule: Mesenchymal Tumor Benign		0/50	(00()	4/50	(00()	0/50	(00()		0/50	(00()	0/50	(00()	0/50	(00/)
Overall Incidence	Total	0/50 1/150	(0%) (0.67%)		(2%) 0.67%	0/50	(0%) 1.15%	Total	0/50 0/150	(0%)	0/50 Moo	(0%) n 0%	0/50 SD	(0%)
Overall incidence	TOLAI	1/150	(0.67 %)	Mean	0.07 %	30	1.13%	Total	0/130	(0%)	iviea	11 0%	30	0%
*Kidney: Renal Tubule: Nephroblastoma		0/50	(00()	0/50	(00()	0/50	(00()		0/50	(00()	0/50	(00()	0/50	(00/)
Overall Incidence	Total	0/50 0/150	` ,	0/50 Mean	(0%)	0/50 SD	(0%)	Total	0/50 0/150	(0%)	0/50 Maa	(0%) n 0%	0/50 SD	(0%)
Overall incidence			` ,		0%	טפ	0%	rotai	0/150	(0%)	iviea	II U%	20	0%
*Kidney: Renal Tubule: Sarcoma					(00()	0/50	(201)			(201)	- /	(224)	0/50	(001)
Overall Incidence	Total	0/50	` ,		(0%)	0/50 SD	(0%)	Total	1/50	(2%)	0/50	(0%)	0/50	(0%)
Overali incidence	Total	0/150	(0%)	Mean	0%	20	0%	Total	1/150	(0.67%)	iviea	n 0.67%	20	1.15%
*Liver: Cholangioma														
		0/50	` ,		(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150	(0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mea	n 0%	SD	0%
*Liver: Hemangiosarcoma		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(00/)	0/50	(09/)
Overall Incidence	Total	0/50	` '	0/50 Mean	` '	0/50 SD	` '	Total	0/50	` ,		(0%) n 0%	0/50 SD	(0%) 0%
Overall moldenee	i Otai	0/100	(070)	ivicari	0 /0	30	0 /0	iotai	0/100	(0/0)	ivica	11 0/0	30	070

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Toxicology Data Management System

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 322

			Male			Female				
Liver: Hepatocellular Adenom	na	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	6/50 (12%)		
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	6/150 (4%)	Mean 4%	SD 6.93%		
Liver: Hepatocellular Carcino	ma				•••••					
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Liver: Hepatocellular Carcino	ma or Hepatob	lastoma				•••••		•••••		
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		
Liver: Hepatocellular Carcino	ma or Hepatoc		4/50 (20/)	0/50 (00/)		0/50 (00/)	0/50 (0%)	6/50 (420/)		
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 6/150 (4%)	0/50 (0%) Mean 4%	6/50 (12%) SD 6.93%		
Liver: Hepatocellular Carcino Hepatoblastoma										
overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 6/150 (4%)	0/50 (0%) Mean 4%	6/50 (12%) SD 6.93%		
Lung: Alveolar/Bronchiolar A	denoma				•••••					
Overall Incidence	Total	4/50 (8%) 6/150 (4%)	1/50 (2%) Mean 4%	1/50 (2%) SD 3.46%	Total	0/50 (0%) 4/150 (2.67%)	4/50 (8%) Mean 2.67%	0/50 (0%) SD 4.62%		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: SKIN Vehicle: ETHANOL

			Male				Female					
*Lung: Alveolar/Bronchiolar Carcinoma 1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)												
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%				
	1 Otal	2/100 (1.00/0)			····							
Lung: Alveolar/Bronchiolar Car Adenoma	cinoma or Alv											
Overall Incidence	Total	5/50 (10%) 8/150 (5.33%)	2/50 (4%) Mean 5.33%	1/50 (2%) SD 4.16%	Total	0/50 (0%) 4/150 (2.67%)	4/50 (8%) Mean 2.67%	0/50 (0%) SD 4.62%				
Lung: Fibrosarcoma		0/50 (004)	0/50 (00/)	0.50 (001)		0/50 (00)	0/50 (00/)	0/50 (00)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
Lung: Sarcoma												
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
Lung: Squamous Cell Carcinon	na					2/22 (22)						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Control Animal Groups Report Date:04/29/2009
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			Male				Female	
#Lymph Node: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Mammary Gland: Adenolipoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (09/)
Overall Incidence	Total	0/30 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/150 (0%)	Mean 0%	0/50 (0%) SD 0%
#Mammary Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Mammary Gland: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	2/50 (4%)	4/50 (8%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	7/150 (4.67%)	Mean 4.67%	SD 3.06%
#Mammary Gland: Carcinoma or Adenoma		(20)	(20)	(20)	•••••	(00)	(00)	(00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 8/150 (5.33%)	3/50 (6%) Mean 5.33%	4/50 (8%) SD 3.06%
#Mammary Gland: Fibroadenoma					•••••			(0.00)
Overall Incidence	Total	3/50 (6%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	0/50 (0%) SD 3.06%	Total	16/50 (32%) 42/150 (28%)	14/50 (28%) Mean 28%	12/50 (24%) SD 4%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female	
#Mammary Gland: Fibroma						
• "' ''	-	0/50 (0%)	0/50 (0%) 0/5	` '	0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0% To	otal 0/150 (0%) Mean 0% SD 0%	
#Mammary Gland: Fibroma, Fibroadenoma	a or Adenoma					
Overell Incidence	Total	3/50 (6%)	1/50 (2%) 0/5	(/	16/50 (32%) 15/50 (30%) 12/50 (24%) otal 43/150 (28.67%) Mean 28.67% SD 4.16%	,
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06% To	otal 43/150 (28.67%) Mean 28.67% SD 4.16%	
#Mammary Gland: Fibroma, Fibroadenoma	a, Carcinoma, o					
		3/50 (6%)	1/50 (2%) 0/5	(/	17/50 (34%) 17/50 (34%) 14/50 (28%)	o)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 3.06% To	otal 48/150 (32%) Mean 32% SD 3.46%	
#Mesentery: Fibrosarcoma		0/50 (0%)	0/50 (0%) 0/9	50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/150 (0%)		SD 0% To		
#Mesentery: Hemangiosarcoma		0/50 (09/)	0/50 (00/)	FO (00()	0/50 (00) 0/50 (00) 0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/5 Mean 0%	` '	0/50 (0%) 0/50 (0%) 0/50 (0%) otal 0/150 (0%) Mean 0% SD 0%	
#Mesentery: Lipoma		0/50 (00)		(()		
Overell Incidence	Total	0/50 (0%)	0/50 (0%) 0/5	` '	0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0% To	otal 0/150 (0%) Mean 0% SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Mesentery: Rhabdomyosarcoma		0/50 (0%)	0/50 (09/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Nose: Adenoma					•••••			(201)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Nose: Chondroma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Nose: Squamous Cell Carcinoma	a	0/50 (00/)	0/50 (001)	4/50 (00)		0(10 (00))	0(50 (00))	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/49 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Oral Cavity (Oral Mucosa, To Papilloma Squamous or P	ngue, Phary	,						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 3/150 (2%)	0/50 (0%) Mean 2%	2/50 (4%) SD 2%
#Oral Cavity (Oral Mucosa, To Squamous Cell Carcinoma	ngue, Phary							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Oral Cavity (Oral Mucosa, Tong Squamous Cell Carcinoma, I Papilloma		Squamous, or						
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 4/150 (2.67%)	0/50 (0%) Mean 2.67%	3/50 (6%) SD 3.06%
Oral Mucosa: Squamous Cell Carcinoma	•••••	0/50 (00()						4/50 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
Oral Mucosa: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
vary: Cystadenoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%
vary: Granulosa Cell Tumor Benig	n					0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence					Total	0/30 (0%)	Mean 0%	SD 0%
ovary: Granulosa Cell Tumor Malig	nant					4/50 (20/.)	0/50 (0%)	0/50 (0%)
verall Incidence					Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male				Female	
*Ovary: Granulosa Cell Tumor:	Benign, Malign	nant, NOS						
Overall Incidence					Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
*Ovary: Granulosa-Theca Tumo					•••••			
Overall Incidence	, Doingi				Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Ovary:								
Granulosa-Theca Tumo	or Malignant					0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenom	na							
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pancreas:			••••••					
Adenoma		0/50 (0%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 3.46%	Total	0/150 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female
*Pancreas: Carcinoma or Adenoma				
Overall Incidence	Total	0/50 (0%) 3/150 (2%)	0/50 (0%) 3/50 (6%) Mean 2% SD 3.46%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Pancreas: Mixed Tumor Benign		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Pancreas: Mixed Tumor Malignant		0/50 (00/)	0/50 (00/) 0/50 (00/)	0/50 (00) 0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Parathyroid Gland: Adenoma				0/43 (0%) 0/46 (0%) 0/45 (0%)
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/49 (0%) 0/49 (0%) Mean 0% SD 0%	0/43 (0%) 0/46 (0%) 0/45 (0%) Total 0/134 (0%) Mean 0% SD 0%
#Peripheral Nerve: Schwannoma Malignant			0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
#Peripheral Nerve: Schwannoma: Benign, Mali	gnant, NOS		0/50 (00/) 0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date:04/29/2009 Vehicle: ETHANOL

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			Male				Female	
Pituitary Gland: Pars Distal Adenoma	is or Unspecif	ied Site:						
		35/49 (71%)	32/50 (64%)	29/50 (58%)		22/50 (44%)	35/50 (70%)	33/50 (66%)
overall Incidence	Total	96/149 (64.43%)	Mean 64.48%	SD 6.73%	Total	90/150 (60%)	Mean 60%	SD 14%
Pituitary Gland: Pars Distal Carcinoma		fied Site:						
		0/49 (0%)	0/50 (0%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
verall Incidence	Total	5/149 (3.36%)	Mean 3.33%	SD 5.77%	Total	3/150 (2%)	Mean 2%	SD 3.46%
Pituitary Gland: Pars Distal		ied Site:						
Carcinoma or Adenoma		35/49 (71%)	32/50 (64%)	34/50 (68%)		22/50 (44%)	35/50 (70%)	36/50 (72%)
verall Incidence	Total	101/149 (67.79%)	Mean 67.81%	SD 3.72%	Total	93/150 (62%)	Mean 62%	SD 15.62%
		,				` ,		
Pituitary Gland: Pars Distal Ganglioneuroma	is or Unspecif	fied Site:						
_		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
ituitary Gland: Pars Intern	nedia:							
Adenoma								
		0/49 (0%)	0/50 (0%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/149 (1.34%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
rituitary Gland: Pars Intern Carcinoma								
		0/49 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 0/49 (0%)(0%)(6%)(0%)(0%)**Overall Incidence** Total 3/149 (2.01%) Mean 2% SD 3.46% Total 1/150 (0.67%) Mean 0.67% SD 1.15% *Prostate: Adenoma 0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** SD 1.15% Total 1/150 (0.67%) Mean 0.67% *Prostate: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)1/50 (2%)Overall Incidence Total 1/150 (0.67%) Mean 0.67% SD 1.15% *Salivary Glands: Sarcoma 0/50 (0%)(0%)1/49 (2%)(0%)0/50 (0%)0/50 0/50 **Overall Incidence** Total 1/149 (0.67%) Mean 0.68% SD 1.18% Total 0/150 (0%) Mean 0% SD 0% **#Seminal Vesicle:** Adenoma 0/50 (0%)(0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% **#Skeletal Muscle: Fibrous Histiocytoma** (0%)(0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 **Overall Incidence** 0/150 (0%) SD 0% 0/150 (0%) SD 0% Total Mean 0% Total Mean 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date:04/29/2009

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		Male				Female	
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) (Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	1/50 (29/)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/30 (0%)	Mean 0%	SD 0%
			••••••				
Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) (Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
habdomyom	a		•••••				
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) (Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	Total Total Total Total	1/50 (2%) Total 1/150 (0.67%) 0/50 (0%) Total 1/150 (0.67%) 0/50 (0%) Total 0/150 (0%) Total 0/150 (0%) Total 0/150 (0%)	O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0% 1/50 (2%) O/50 (0%) Total 1/150 (0.67%) Mean 0.67% O/50 (0%) O/50 (0%) Total 1/150 (0.67%) Mean 0.67% O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0% nabdomyoma O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0% O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0%	O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total 0/150 (0%) Mean 0% SD 0% 1/50 (2%) 0/50 (0%) 0/50 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% 0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Total 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) D/50 (0%) 0/50 (0%) Total 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total Total 0/50 (0%) 0/50 (0%) Mean 0.67% SD 1.15% Total Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total Total	O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total O/150 (0%) Mean 0% SD 0% Total O/150 (0%) 1/50 (2%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total O/150 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total O/150 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total O/150 (0%) Total 0/150 (0%) Mean 0.67% SD 0% Total 1/150 (0.67%)	Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/150 (0%) 0/50 (0%) Mean 0% Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% Total 1/50 (2%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) 0/50 (0%) Mean 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) Mean 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) Mean 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%) Mean 0% Total 0/150 (0%) 0/50 (0%) Mean 0.67% SD 0/50 (0%) Total 0/150 (0%) Mean 0% Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Skin: Basal Cell Adenoma		0/50 (00/)	0/50 /00/	0/50 /00/)		0/50 /00/	0/50 /00/	0/50 (00/)
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin:	_							
Basal Cell Adenoma or	Basosquamou	•	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
	Total	0/150 (0%)	Mean 0%		Total	0/150 (0%)	Mean 0%	
Skin: Basal Cell Adenoma, B Trichoepithelioma	asosquamous '	Tumor Benign, or						
•		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin:								
	or Basosquamo	ous Tumor (malignant or	r					
NO3)		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
				OD 070	1 O.U.		wican 070	
Skin: Basal Cell Carcinoma, Tumor (benign, malign		Trichoepithelioma	2/22 (22)			2/22 (22)		(20)
verall Incidence		1/50 (2%)	0/50 (0%)	0/50 (0%)	_	0/50 (0%)	0/50 (0%)	0/50 (0%)
	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

				Ma	ale					Female	
Skin: Basal or Sq. Cell Carcino or B), Basal Cell Adenom Papilloma, Keratoacanth	na, Adenoma,	Papilloma, S pithelioma		2/50	(4%)	4/50	(8%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
verall Incidence	Total	8/150 (5	` '		5.33%		2.31%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
Skin: Fibroma	•••••					•••••					
Overall Incidence	Total	1/50 13/150 ((2%) (8.67%)		(14%) 8.67%	5/50 SD	(10%) 6.11%	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%
Skin: Fibroma, Fibrosarcoma, Fibrous Histiocytoma	Sarcoma, My	xoma, M yxos 3/50 16/150 ((6%)		(16%) 10.67%	5/50 SD	(10%) 5.03%	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%
Skin: Fibrosarcoma		······································									
Overall Incidence	Total	2/50 2/150 (1	(4%) .33%)		(0%) 1.33%	0/50 SD	(0%) 2.31%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin:										0/50 (00)	
Fibrosarcoma, Sarcoma, Histiocytoma		0/50	(40/)						0/50 (0%)	0/50 (0%)	0/50 (0%)
Histiocytoma	Total	2/50 3/150 (2	(4%) 2%)	1/50 Mean	(2%) 2%	0/50 SD	(0%) 2%	Total	0/150 (0%)	Mean 0%	SD 0%
		3/150 (2	2%)	Mean	2%	SD	2%		0/150 (0%) ´	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male				Female	
#Skin: Hemangioma Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall incluence	ı Olai	0/130 (0/8)	ivican 070		ı Olai	0/130 (0/8)	ivieaii 076	
#Skin: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Keratoacanthoma		0/50 (004)	0/50 (404)			0/50 (00)	0/50 (00/)	4/50 (001)
Overall Incidence	Total	0/50 (0%) 5/150 (3.33%)	2/50 (4%) Mean 3.33%	3/50 (6%) SD 3.06%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Skin: Lipoma		0/50 (00/)	4/50 (00)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Liposarcoma		2/22 (201)						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neural Crest Tumor		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Vehicle: ETHANOL

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

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			Male				Female	
#Skin: Neural Crest Tumor, Mali	gnant	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Skin: Neurofibroma or Schwan								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neurofibrosarcoma or Sc	:hwannoma (r	malignant or NOS) 1/50 (2%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
#Skin: Neurofibrosarcoma, Neur malignant or NOS)	rofibroma, or	Schwannoma (benign,						
Overall Incidence	Total	1/50 (2%) 5/150 (3.33%)	2/50 (4%) Mean 3.33%	2/50 (4%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
#Skin: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Schwannoma Benign		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

			Male				Female	
#Skin: Schwannoma Malignant				-/		(00)	2/22 (221)	2/52 (194)
Overall Incidence	Total	1/50 (2%) 4/150 (2.67%)	1/50 (2%) 2 Mean 2.67%	2/50 (4%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
#Skin: Squamous Cell Carcino	ma							
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) (Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Skin: Squamous Cell Carcino Basosquamous Tumor (0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Squamous Cell Papillom	na	0/50 (00/)	0/50 (00)	4/50 (00/)		0/50 (00/)	0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Squamous Cell Papillon	na or Papillom		0/50 (00)	4/50 (00/)		0/50 (004)	0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Squamous Cell Papillom Carcinoma or Keratoaca		Squamous Cell						
Overall Incidence	Total	1/50 (2%) 7/150 (4.67%)	2/50 (4%) 4 Mean 4.67%	4/50 (8%) SD 3.06%	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Squamous Cell Papilloma,	Papilloma,							
Overall Incidence	Total	0/50 (0%) 6/150 (4%)	2/50 (4%) Mean 4%	4/50 (8%) SD 4%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Skin: Trichoepithelioma		4/50 (20/)	0/50 (00/)	0/50 (0%)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Sebaceous Gland: Adenoma		0/50 (00/)	0/50 (00)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Sebaceous Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (00/)	0/50 (00)	4/50 (001)		0/50 (00)	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Spinal Cord: Astrocytoma Benign		0/50 (00/)	0/50 (00)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

e: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Route: SKIN Vehicle: ETHANOL

			Male				Female	
#Spinal Cord: Astrocytoma Malignant		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Spinal Cord: Glioma Malignant		0/50 (0%)	0/50 (00/)	0/50 (0%)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Spleen: Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Spleen: Fibrous Histiocytoma	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma	•••••	0/50 (00/)	0/50 (00/)	0/50 (0%)		0/50 (00/)	0/50 (09/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Spleen: Hemangiosarcoma	•••••	0/50 (00()	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
Spleen: Leiomyosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 /00/3	0/50 (00/)	0/50 (00/)
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Spleen: Sarcoma		4/50 (00)	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Stomach, Forestomach: Leiomyosarcoma		0/50 (00)						
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
tomach, Forestomach: Squamous Cell Carcinom		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)		
verall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
tomach, Forestomach: Squamous Cell Carcinom	a or Papillon		4/50 (004)	4/50 (004)		0/50 (00)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
tomach, Forestomach: Squamous Cell Papilloma								
verall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Stomach, Glandular: Lipoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Stomach, Glandular: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Testes: Adenoma		30/50 (60%)	37/50 (74%)	36/50 (72%)				
Overall Incidence	Total	103/150 (68.67%)	Mean 68.67%	SD 7.57%				
*Thymus: Sarcoma		0/49 (0%)	0/49 (0%)	0/49 (0%)	•••••	0/49 (0%)	0/45 (0%)	0/50 (0%)
Overall Incidence	Total	0/147 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Benign		0/40 /09/\	0/40 (0%)	0/40 (09/)		0/49 (0%)	0/45 (09/)	0/50 (00/)
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/49 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/49 (0%) 0/144 (0%)	0/45 (0%) Mean 0%	0/50 (0%) SD 0%
*Thymus: Thymoma Malignant								
Overall Incidence	Total	0/49 (0%) 0/147 (0%)	0/49 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/49 (0%) 0/144 (0%)	0/45 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male	Female
*Thymus: Thymoma NOS		0/49 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%) 0/45 (0%) 0/50 (0%)
Overall Incidence	Total	0/147 (0%)	Mean 0% SD 0%	Total 0/144 (0%) Mean 0% SD 0%
*Thymus: Thymoma: Benign, Maligna	nt, NOS	0/49 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%) 0/45 (0%) 0/50 (0%)
Overall Incidence	Total	0/147 (0%)	Mean 0% SD 0%	Total 0/144 (0%) Mean 0% SD 0%
*Thyroid Gland: C-Cell: Adenoma	•••••	10/50 (20%)	10/50 (20%) 5/50 (10%)	6/50 (12%) 8/50 (16%) 3/50 (6%)
Overall Incidence	Total	25/150 (16.67%)	Mean 16.67% SD 5.77%	Total 17/150 (11.33%) Mean 11.33% SD 5.03%
*Thyroid Gland: C-Cell: Carcinoma		1/50 (2%)	2/50 (4%) 5/50 (10%)	0/50 (0%) 0/50 (0%) 2/50 (4%)
Overall Incidence	Total	1/50 (2%) 8/150 (5.33%)	2/50 (4%) 5/50 (10%) Mean 5.33% SD 4.16%	0/50 (0%) 0/50 (0%) 2/50 (4%) Total 2/150 (1.33%) Mean 1.33% SD 2.31%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma				
Overall Incidence	Total	11/50 (22%) 33/150 (22%)	12/50 (24%) 10/50 (20%) Mean 22% SD 2%	6/50 (12%) 8/50 (16%) 5/50 (10%) Total 19/150 (12.67%) Mean 12.67% SD 3.06%
*Thyroid Gland: Follicular Cell: Adenoma		0/50 (00/)	0/50 /00/) 4/50 /00/)	4/50 (00) 0/50 (00) 0/50 (00)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) 1/50 (2%) Mean 0.67% SD 1.15%	1/50 (2%) 0/50 (0%) 0/50 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male				Female	
*Thyroid Gland: Follicular Cell: Carcinoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma		0/50 (00/)	4/50 (00)	4/50 (00)		0/50 (40/)	0/50 (0%)	4/50 (00()
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	2/50 (4%) 3/150 (2%)	0/50 (0%) Mean 2%	1/50 (2%) SD 2%
#Tissue NOS: Lipoma		0/50 (00/)	0/50 (00/)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Tissue NOS: Paraganglioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 /00/	0/50 (0%)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Tongue: Squamous Cell Carcinoma		0/50 (/0//)	0/50 (0%)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Tongue: Squamous Cell Carcinoma	or Papillon							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
#Tongue: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
#Tooth: Adamantinoma Malignant		0/50 (00()	0/50 (00)	0/50 (004)		0/50 (00/)	0/50 (00)	0/50 (00()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Tooth: Odontoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Urinary Bladder: Carcinoma	•••••	0/50 (00/)	0/50 (001)	0/50 (004)		0/50 (004)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Urinary Bladder: Carcinoma or Papilloma						2/22 (221)		
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
Jrinary Bladder: Hemangiosarcoma		0/50 /00/	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (09/)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
rinary Bladder: Leiomyosarcoma		0/50 (00/)						
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
rinary Bladder: Papilloma	•••••	0/50 (00/)	0/50 (00()	0/50 (00/)		0/50 (00)	0/50 (00()	0/50 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
terus: Adenoma						0/50 (00)	0/50 (00()	0/50 (00/)
verall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
terus: Carcinoma	•••••							
verall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
terus: Deciduoma Benign								
verall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Vehicle: ETHANOL

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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	Male			Female	
#Uterus: Hemangioma					
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Hemangiosarcoma					
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Leiomyoma					
Overall Incidence		Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Uterus:					
Leiomyosarcoma			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/30 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal				•••••	
Overall Incidence		Total	5/50 (10%) 17/150 (11.33%)	2/50 (4%) Mean 11.33%	10/50 (20%) SD 8.08%
#Uterus: Sarcoma Stromal			1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence		Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Uterus: Sarcoma Stromal or Po	lyp Stromal							
Overall Incidence					Total	6/50 (12%) 19/150 (12.67%)	3/50 (6%) Mean 12.67%	10/50 (20%) SD 7.02%
#Uterus: Schwannoma Malignan			•••••					
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Vagina: Polyp			•••••	•••••				
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Vagina: Sarcoma								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Zymbal's Gland: Adenoma			•••••					
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Zymbal's Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

#Zymbal's Gland:

Overall Incidence

Contract/Lab: All Laboratories

Species: RATS

Strain: F344 Length of Study: CHRONIC

Carcinoma or Adenoma

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ETHANOL

Male				Female	
0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Mean 0.67%	SD 1.15%		0/150 (0%)	Mean 0%	SD 0%

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Total

1/50

1/150 (0.67%)

(2%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied